



Derouging and Repassivation

Removal of discolourations in
purified steam and ultrapure
water systems.

Formation of Rouge.

Equipment in the pharmaceutical and biotechnology industries, such as tube systems for ultrapure water (AP, PW, HPW, WFI, etc.), WFI distillers, storage tanks, purified steam systems, etc. usually consist of austenitic stainless steel (e.g. 1.4404/1.4435/316L, etc.).

After consistently short operating periods, the inner surfaces of these systems, which are often operated hot, show red-brown contamination, which can be easily detected with a white cloth test. These are usually heavy metal particles resulting from a change in the stainless steel surface, so-called rouging.

Downstream production systems such as fermenters, batch and mixing vessels, together with their tube systems, are contaminated by the spread of the rouge particles. Even with the regular CIP cleaning of these systems, the heavy metal particles cannot be cleaned off in a way that will last a long period of time.

Customised Derouging.

Expert derouging should be planned in the long term. Optimised cleaning methods in conjunction with active rouge monitoring allow for ratios that correspond to effective rouge avoidance.

Derouging operations are carried out by our specially trained on-site teams for the GMP-relevant area. Only state-of-the-art equipment and safety technologies are used. The cleaning chemicals are specially developed for use on sensitive pharmaceutical plants. All work is thoroughly documented and the used chemical solutions processed in an environmentally responsible and professional manner with certificate.

Bioderouging.

Our bioderouging solutions are aqueous organic salt solutions in a pH-neutral range. Depending on the nature and intensity of the present rouge deposit, the pH-neutral solutions will be between 1 and 10% by weight at 40 to 90°C over 1 to 8 hours.

The practical application on-site is such that the tank/tube system to be derouged is filled with the solution, which is then circulated at high temperatures. Discharge into a biological sewage treatment plant after consultation with the person responsible for discharge may be possible without further pretreatment.

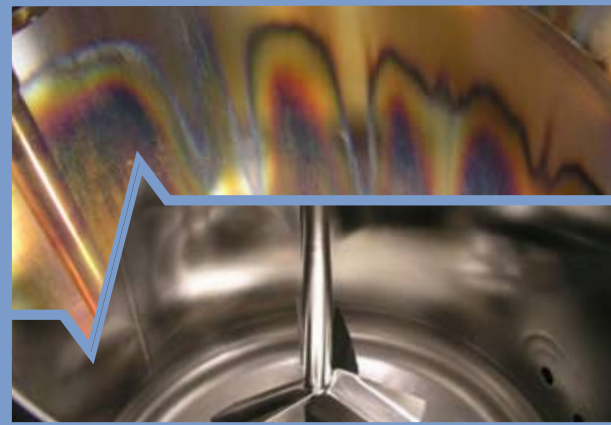
Wet-chemical Passivation

The corrosion resistance of stainless steel is based on the formation of a very thin chromium oxide-rich passive layer, which is formed only on metallurgically pure stainless steel surfaces. Thermal, chemical or mechanical processing affect the formation of the passive layer.

Passivation of the stainless steel surface is therefore highly recommended after any chemical surface treatment, such as derouging as a final processing step.

The passivation solution helps with the renewal of the chromium oxide layer of the stainless steel surfaces. In addition, the layer structure with wet-chemical passivation is more homogeneous. After this kind of repassivation treatment, the surface is completely passive and ready for use again.

Pharmaceutical tank before and after derouging treatment by HENKEL.



HENKEL-Surfaces Assure Your Component's Value.

Our Service Range

- * On-site and factory service
- * Electrochemical polishing
- * Anodic cleaning
- * Chemical polishing / deburring
- * Chemical pickling and passivation
- * Professional cleaning (also in clean room)
- * Derouging and re-passivation
- * Rouge monitoring
- * Process and cleaning chemicals



HENKEL Beiz- und Elektropolieretechnik

Waidhofen-Thaya (AT) | Győr (HU) | Neustadt-Glewe (DE)

info@henkel-epol.com | www.henkel-epol.com



HENKEL Passive Layer Guard.

We have developed the HPLG, a rouge measuring instrument that detects the change in the passive layer in the wetted surface area, in order to plan maintenance tasks in pharmaceutical ultrapure water systems at an early stage.

With this inline monitoring system, operators of ultrapure water systems are able to detect depassivation and formation of a layer of rouge at an early stage without having to open the system. The time of the unmonitored rouge particle emission can be determined beforehand and therefore the budget for maintenance measures can be optimised. The operator receives information promptly to allow reconditioning measures such as derouging and repassivation with defined surface conditions.

The Measuring Principle.

The HENKEL Passive Layer Guard is an optoelectronic measuring system that detects the process of depassivation and rouge formation and enables the surface condition of a tube system to be monitored.

These changes are compared reproducibly with electronically saved surface conditions. The information (degree of rouging) is shown as a colour display on the device or is transmitted via the interface cable to the central measurement data acquisition.

Implementation in accordance with GMP.

To ensure a high quality standard, we always work according to good manufacturing practices:

- * Permanent on-site team for maximum reliability
- * GMP-trained staff for the pharmaceutical and biotechnology industries
- * Work in line with tested and approved SOPs
- * Documentation in accordance with GMP
- * Full traceability of the chemical batches
- * The chemicals used are completely soluble in water and easy to detect through measurement of pH value or conductivity

Materials.

The composition of the metallic alloy has a considerable influence on the chemicals used. The HENKEL derouging and repassivation chemicals can be used, for example, on the following materials:

Stainless steels (including 1.4404/1.4435/316L, 1.4539/904L, etc.), duplex stainless steels.

Your benefits.

In addition to HENKEL's proven quality, you receive extensive additional benefits with a derouging application:

- * Rapid restoration of surface conditions in accordance with the defined specifications
- * Efficient technologies
- * Experienced staff
- * State-of-the-art technical apparatus and safety technology
- * Documentation and chemicals in accordance with GMP
- * Expert processing of waste water
- * Two derouging methods: acidic ($\text{pH} < 1$) or bioderouging and biopassivation



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