

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 redbrown 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.

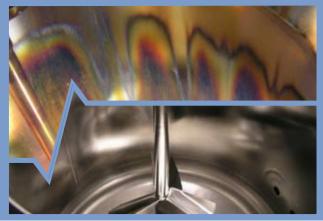
The practical application on-site is such that the tank/tube system to be derouged is filled with the solution, which is then circulated at high temperatures. Discharge into a biological sewage treatment plant after consultation with the person responsible for discharge may be possible without further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

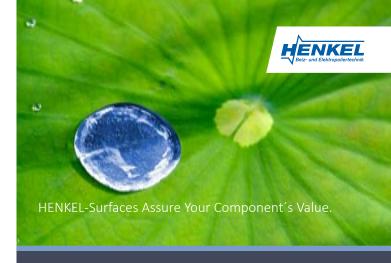
Electrochemical Derouging.

For removing coatings and scratches, surfaces can be chemically derouged as well as anodically or electrochemically cleaned. Both processes are effective, but differ in terms of processing time and the final result. The anodic process (similar to electropolishing) usually improves the surface considerably, as not only the coatings but also material in the micrometre range are removed from the surface (5-10 μ m). This results in a so-called micro-smoothing of the surface, which, among other things, greatly reduces the tendency to form coatings. A further advantage is the significantly reduced use of chemicals.

Electrochemical derouging can be used with almost all vessel sizes. Only tube systems cannot be processed with this procedure.

Pharmaceutical tank before and after derouging treatment by HENKEL.





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 repassivation
- | Process and cleaning chemicals
- Documentation
- Construction





HENKEL Beiz- und Elektropoliertechnik

Waidhofen-Thaya (AT) | Györ (HU) | Neustadt-Glewe (DE) info@henkel-epol.com | www.henkel-epol.com



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 metallically 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. The layer structure with wet-chemical passivation is more homogeneous. In addition, wet-chemical passivation is a controlled, reproducible process because the build-up of air oxygen is highly dependent on the ambient atmosphere.

After this kind of repassivation treatment, the surface is completely passive and ready for use again.

In addition to our standard passivation solution, we also offer citric acid biopassivation.

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 (pH < 1) or bioderouging and biopassivation



Derouging and Repassivation

Removal of discolourations in purified steam and ultrapure water systems.