

# Abstract

## Study of stainless steel corrosion in pharmaceutical facilities: Initiation and development

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Production and distribution equipment for clean utilities used in pharmaceutical industries are usually made of 316L austenitic stainless steel. Vessels and pipes undergo cyclic phases of production and sanitisation where the temperature can reach 95°C (hot purified water) or 121°C (pure steam).

In these extreme conditions, the stainless steel surface is slowly modified. The chromium-rich passive oxide layer evolves to become a high iron content layer. This involves a change of colour from metallic to red and, in the worst case, to black. This phenomenon is called Rouging.

Stainless steel corrosion may have several incidences like release of iron in the media or product. Moreover, the Good Manufacturing Process (GMP) requires that a surface with product contact has to be visually clean. In the end, pharmaceutical facilities may become unsuitable to produce vaccines and drugs.

Rouging has been known for a long time but surprisingly it is poorly studied.

This research project has several objectives: (i) to describe the evolution of the passive layer of stainless steel in contact with hot fluids; (ii) to understand the mechanisms of rouge formation and (iii) to define the incidence of rouge on surface properties.

For this purpose, several experiments were designed. The first one is described in this presentation. The goal is to study the interaction between a passive layer and a hot fluid. Two classical grades of austenitic stainless steel are used: AISI 304L and 316L. Several types of surface preparations are tested. Some samples are placed under standard condition (nitric or citric passivation, electropolishing). In order to fully understand the mechanisms of passive layer transformation, other samples are polarized with specific electrochemical conditions. All samples are placed in reactors half filled with different hot media. Some of them are in the liquid part, the others in the gaseous part at different temperatures to study the influence of fluid nature. The evolution of passive layer is followed at different immersion times with SEM (coupled with EDS/WDS), XPS, SIMS, XRD and TEM. SEM provides a topographic analysis, allowing the observation of physical evolution of passive layer with chemical elemental characterisation. XPS provides the oxidation state and elemental analysis of a small area presented as depth profile. XRD provides crystallographic information about passive layer. TEM provides local chemical analyses and crystallographic information.