How to Ensure the Right Finish for Mixers used in High Purity and Sanitary Processes

Admix Inc. has extensively used stainless-steel alloys to fabricate mixing and blending equipment for the food, beverage, cosmetic and pharmaceutical industries. Admix recognizes that, to meet the high standards of purity and cleanliness demanded by the pharmaceutical and biopharmaceutical industries, it is necessary to use 316 stainless-steel as the material of construction for not only the wet end portion of the mixer, but also for portions of the drive end, which may include the motor, bearing frame or gear box.

It is also important that mixer and blender surfaces are smooth and clean, to minimize microbial contamination, reduce erosion corrosion and prevent the adherence of particulates to the surfaces of the equipment. The required surface characteristics may be obtained by electropolishing or by using either a mechanical or chemical treatment. Without question, the smoothness of the surfaces of mixers and blenders are of concern and therefore, as part of the fabrication of their mixers and blenders, Admix routinely mechanically polish, electropolish and passivate those surfaces that contact the materials being processed.

A comprehensive inventory for sanitary standards and accepted manufacturing practices for the dairy, beverage and food processing industries has been established by 3-A Sanitary Standards Incorporated (3-A SSI)[1]. Accredited by the American National Standards Institute (ANSI), the 3-A guidelines for hygiene, safety and manufacturing practices are consistent with those established by agencies such as the USDA-Dairy, USDA-AMS and AG-Canada. The 3-A symbol displayed on process equipment shows compliance with those established standards, with regard to the materials of construction, design and fabrication.

In 2003, 3-A introduced a program to verify that process equipment met the established standards and Admix has aggressively pursued conformance under this program. The new 3-A TPV number (which is also displayed on the equipment) and a certificate is issued to indicate that compliance has been independently verified by a certified conformance evaluator, resulting from a detailed inspection of all components on each machine at the manufacturer's facilities[2]. 3-A SSI TPV certificates have been issued to Admix[3] for their complete line of high shear and low shear, top entry mixers, as well as several models of dispersers and blenders designed for in- line processing on either a continuous or semi-continuous basis.

Within the 3-A manuals it is stated that the surfaces of process equipment --- particularly those surfaces that contact the materials being processed --- should be smooth, corrosion resistant, impervious, free of cracks and crevices, non-absorbent, non-toxic and cleanable. To meet these guidelines the stainless-steel alloys have become the preferred materials of construction, being readily available and easily fabricated

into complex structures. Furthermore the alloys provide superior corrosion resistance to mild steel or carbon steels, and the required surface properties can be obtained by a combination of mechanical or chemical polishing, electropolishing and passivation.

Presently, Admix favors using the 316 stainless-steel alloy for the construction of blenders and mixers, particularly for use in the pharmaceutical and biopharmaceutical industries. The 316 alloy contains molybdenum (2-3%), added to provide resistance to general corrosion that is superior to that of the 304 and 304L alloys more commonly used in the processing industries. The high purity requirements of the pharmaceutical and biopharmaceutical industries justify this position, especially for the equipment used in the production of Active Pharmaceutical Ingredients (APIs) and related materials and should comply with ASME-BPE standards (directed to bioprocess equipment) and 3-A sanitary standards (directed to the food, beverage and dairy industries). Admix will continue to aggressively pursue compliance under the new guidelines as they are developed for mixing equipment.

Why are smooth surfaces important?
Not only visually attractive, smooth surfaces can minimize the accumulation of products at the metal surfaces during mixing and other processing steps. Furthermore, the surfaces can be cleaned easily and effectively since there are fewer sites available for the growth of microbial contaminants. Perhaps more significantly, the rate of general corrosion of the metal depends upon the real surface area that is exposed to the corrosive environment. A smooth surface has a significantly lower, real area and therefore a lower rate of corrosion. In addition, the smooth surface reduces erosion corrosion, i.e., the loss of metal from the surface due to the flow of the process fluids.

How are smooth surfaces obtained?
The surfaces of the stainless-steel parts may be polished to a smooth finish by mechanical or chemical treatments or by electropolishing.

Mechanical surface treatments of the stainless-steel alloys include the use of abrasive compounds, grinding and buffing processes, sandblasting with silica, as well as shot, grit and wire blasting using stainless-steel media. These methods are carried out carefully to avoid contamination of the polished surface with iron containing materials. Furthermore, the parts that are polished mechanically are not as resistant to corrosion as those treated chemically or electropolished, due probably to the loss of chromium from the surface layer. Several of the basic stainless-steel mill plate finishes may be obtained by mechanical polishing. For example, the #4 polished finish (required to meet the basic 3-A standards for the processing industries) is obtained using a 120- 150 mesh abrasive and is a general-purpose bright finish. The #7 and #8 finishes are highly reflective finishes that are obtained by polishing and buffing the surface with a series of fine abrasives.

Chemical Surface Treatment, also referred to as chemical polishing and steel pickling[4], is required to remove the scale formed at the surface of the steel during the hot rolling and annealing processes. Pickling is carried out by either the immersion of the part in a pickling bath or by coating the surface with a pickling paste. Presently a solution of hydrochloric acid is the preferred pickling bath, providing faster reactions, greater flexibility, better quality control and lower costs. The pickling bath is typically heated to temperatures between 35 and 45˚C and the length of time of the treatment is dependent upon the thickness and composition of the scale. Chemical treatment is also used to remove the debris (scale) from the surface of the steel, debris from grinding operations, abrasives and buffing compounds that can promote pitting and crevice corrosion. The presence of particles of iron on the alloy surface results in the formation of "rouge," a red-brown film of iron oxide. This film may be physically wiped from the surface of the alloy, but if the iron particles are not completely removed, the oxide layer is quickly reformed. The presence of surface "rouge" is a concern when high purity is required, and the part is usually chemically cleaned. The presence of impurities in or on the surface can also interfere with passivation of the steel substrate.

Electropolishing[5] uses an electric current to uniformly dissolve the surface layers of the metal and has been termed "electroplating in reverse." Large and irregularly shaped parts are rapidly and efficiently polished electrolytically, though not necessarily at a lower cost than mechanical polishing. In electropolishing the substrate acts as the anode in the cell and is immersed in an electrically conductive solution, which is usually an aqueous solution containing mixtures of inorganic acids and organic additives. A counter electrode (the cathode in the cell) is also immersed in the electrolyte to complete the circuit and allow current to flow. The rate of dissolution of the metal is proportional to the applied current and the amount of metal electrochemically dissolved depends upon the composition of the electrolyte, time, temperature and the current density (the applied current divided by the surface area of the part). The method is particularly suitable for components that have complex geometries, e.g., the impellers in mixers, or components that are easily damaged. The configuration of the counter electrode can be critical, particularly when the part is an irregular shape, since it is necessary to provide the required current density across the whole surface being polished. Experience also teaches that both the effects of gas evolution from the cathode can adversely affect the surface finish and it is necessary to use anions or solvent molecules that are difficult to discharge or to provide controlled agitation.

What is passivation?

Passivation refers to the formation of a film of chromium oxide, by the reaction of chromium atoms in the surface of the steel with atmospheric oxygen[6]. This film acts as a protective layer on the steel substrate and inhibits general corrosion reactions, enhancing the long-term performance of the equipment. The stainless-steel alloys are often passivated to ensure that the process equipment meets the required standards for purity. The presence of impurities in or on the surface of the alloy can interfere with the formation of the passive, chromium oxide layer and therefore passivation is usually preceded by a

chemical treatment or electropolishing.

How is surface smoothness measured?

Surface smoothness, or conversely surface roughness has been described in various ways, e.g., grit numbers, USA finish numbers, RMS, Ra (microinches) or Ra (microns). However, to allow specification of surface finishes for stainless-steel equipment, a method has been adopted that conforms to the ANSI/ASME standard, B46.1. The surface roughness is measured with a profilometer, an instrument that uses a sensitive, diamond-tipped probe to trace the peaks and valleys as it moves across the surface. The roughness is then expressed as the arithmetic mean of the departure of the peak heights and valley depths from a center line and the profile is recorded over several sampling lengths to obtain an average value. This average is termed the Ra value and is expressed in microinches[7]. The table below compares grit numbers, USA finish numbers and common names of surface finishes with the Ra number obtained using the profilometer.

Table 1. Terminology for Surface Finishes.

Polish	Grit	Ra (Microinch)	Ra (Micron)
#3	#80	50	--
#4	#150	30-35	0.76-0.89
#4	#180	20-25	0.50-0.65
#6	#240	15-20	0.375-0.50
#7	#320	8-12	0.20-0.30
#8	#400	4-8*	0.10-0.20

** Ra (Microinch) values of 4-8 are typically obtained by electropolishing.*

Which surface treatment is preferred by the process industries?

The high purity of pharmaceutical and biopharmaceutical processes and their sensitivity to traces of metal impurities requires the surfaces of the mixing and blending equipment to be very smooth (“mirror finish”). As stated earlier, electropolishing can be used effectively with large, irregularly shaped parts and the resulting surfaces are bright, very smooth, stress relieved and free of impurities. However, economics may dictate the use of abrasives and buffing compounds, but then it is essential to clean the surfaces of iron oxide and debris using a chemical treatment. Passivation may be selected as a final treatment to improve the long-term performance of the equipment.

Why select mixing equipment manufactured by Admix?

The mixers, blenders, dispersers and emulsifiers manufactured by Admix Incorporated comply with the most stringent hygienic and safety standards and are fabricated from stainless-steel alloys to provide the required corrosion resistance.

Furthermore, Admix will continue to aggressively pursue compliance as new standards are developed for

the pharmaceutical and biopharmaceutical industries. The impellers incorporated into the mixers are individually fabricated and offer significant advantages over cast units.

The importance of surface smoothness, particularly the smoothness and cleanliness of surfaces that contact the materials being processed, is well understood by the engineers and fabricators at Admix. All surfaces are mechanically polished to <20 Ra, electropolished and passivated. Admix is continually solving mixing and dispersion problems through their unrivaled expertise and remain true to their stated mission:

"To be the best resource for sanitary mixers, dispersers, emulsifiers and particle size reduction equipment."

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