Optimization of Cleanability

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As a general rule, the ultimate effort to avoid chemical and microbiological "cross contamination" is to attain maximum improvement of cleaning and sterilization procedures and methods for application in manufacturing and reconditioning equipment. According to current good manufacturing practices, the critical contact equipment should be manufactured of stainless steel with a sanitary finished surface which, as will be shown later, by no means represents the best option to minimize contamination.

Contamination, deriving from bacteria and particles, generally is microscopic in nature, thus making it essential to conduct the required observation and analysis of the product contact surfaces on the same scale.

Bacteria and Particles

Figure 1 shows how a sanitary finished surface may be viewed

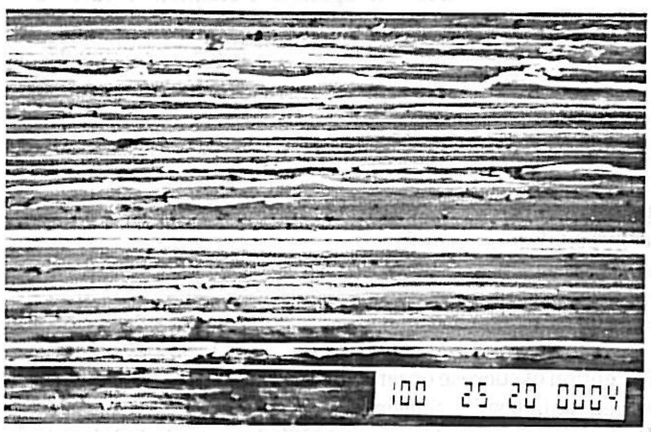

Figure 1. Sanitary finish, (750X).

under a microscope. It resembles a succession of valleys and peaks approximately 2 μm in height, appearing as if they had been specifically designed to hide contaminating substances.

Bearing in mind the fact that bacteria measure from 0.3 to 40 μm, and further taking into consideration the inherent lack of uniformity of mechanical processes with which sanitary finished surfaces are produced, we cannot but express our dissatisfaction with the quality of such a finish.

An abrasive finished surface is misleading in nature due to the polishing mechanical action which produces it. There is not only removal, but also superficial flow or smearing of metal. This phenomenon creates folds which are non-detectable to the naked eye and are generally overlooked when surface inspections are conducted with a roughness tester (an instrument designed to register and amplify signals deriving from a very fine phonographic-type needle when it moves across the tested surface).

Figure 2 shows in a vertical or profile cut view a portion of

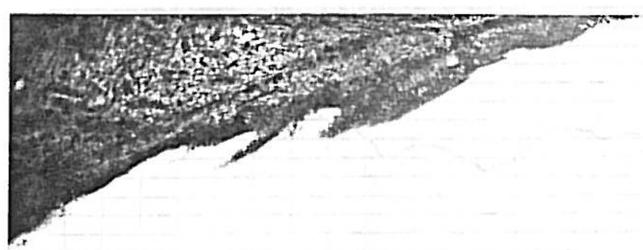

Figure 2. Typical defects of sanitary finishes, (350X).

what might be the bottom of a container. The shape and dimensions of the resulting abnormalities and defects have not been exaggerated. They correspond to typical defects found in an apparently perfect sanitary surface. Each square centimeter of such surface may well entrap one half milligram (½ mg.) of contaminating substances. Further contaminants may easily be concealed within fissures or cracks of a welding bead with the following dimensions: 2.5 mm length, 0.2 mm width and 1 mm depth. Such fissures and cracks are many times ignored and overlooked in any surface finished with abrasives.

Such circumstances as described above, explain the presence of a multitude of stains found after operating or using some processing and storage tanks.

Shape Concept of a Surface

The problem of retention of contaminants cannot be solved efficiently and economically simply by improving the mechanical polishing operation. Such a remedy will merely reduce dimensions of abnormalities without modifying their shape. The only effective way to successfully eliminate the microscopic steel burrs, folds and any microscopic abnormalities is through application of the *electropolishing* finishing process. This process consists of an electrolytic system designed to remove metal. Peaks are dissolved quicker than valleys as a result of the greater concentration of current over the protuberances. This action produces a smoothing operation that provides a rounded finish surface profile, free from any abrupt changes and stresses.

It is not difficult to see that the electropolished surface (as illustrated in Figures 3a and 3b) due to its rounded profile finish

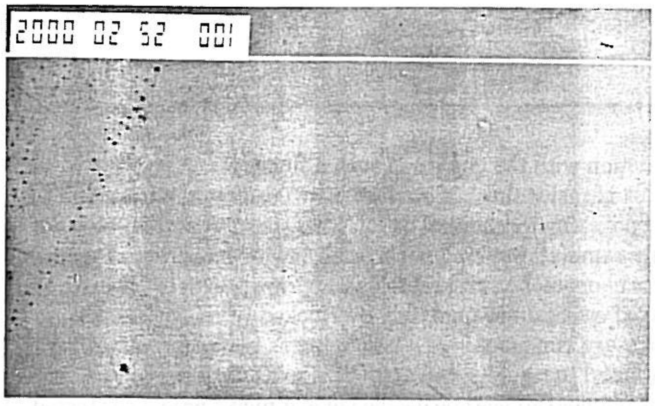

Figure 3a. This surface was mechanically polished to 120 grit and then electropolished, (750X).

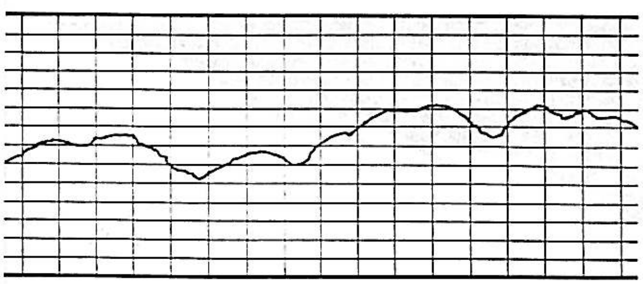

Figure 3b. Surface profile. Mechanically polished to 120 grit and electropolished. Ra = 0.30 μm.

is easier to clean than the surface illustrated in Figure 4,

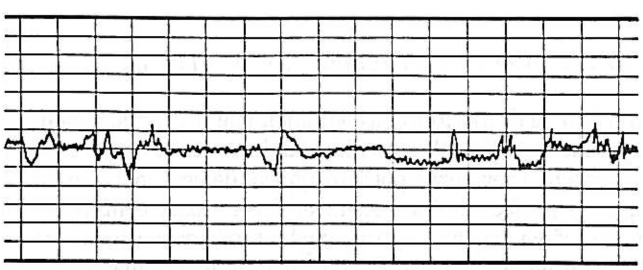

Figure 4. Profile of mechanically polished surface. Ra = 0.15 μm.

although the latter shows a rather lesser degree of abnormalities and defects than the former[1]. The advantage of exceptionally good cleaning feasibility for a rounded finish surface has been verified both in laboratory practice and in regular plant operation.

Laboratory Tests

Jordan[2] conducted tests relating to cleaning feasibilities of various stainless steel plates having different surface finishes. He used contaminant matter containing radioactive bacteria (isotope^{32}P). After uniformly contaminating and later cleaning the plates, Jordan measured radioactivity on each one of them.

Table I shows results corresponding to four (4) of the finishes most frequently found in our field.

Finish	Surface Roughness Factor, Ra (μ m)	Radioactivity (cpm)
No. 8 (mirror)	0.01 to 0.03	71
2 B (cold rolled)	0.20 to 0.50	611
No. 4 (sanitary finish)	0.20 to 0.30	124
Electropolished	0.18 to 0.22	72

Table I.

As can be seen from Table I, the three latter mentioned finishes, although having a similar level of rugosity, have different cleanability. On the other hand, No. 8 and *electropolished* finishes evidenced practically the same degree of cleansing feasibility. However, in order to thoroughly reach the rugosity value corresponding to the No. 8 finish, which shows a tenfold less rugosity level than relative to that of the *electropolished* surface, a long and costly mechanical process is required and has practical application only for small and flat pieces.

A much simpler and objective test was conducted recently by Milledge[3]. He specifically conducted studies to determine the exact amount of sucrose solution being retained by several stainless steel plates having different surface finishes, when solution has allowed to drip onto plates in various inclined positions.

Table II reflects certain data reproduced from a wide assortment of test results obtained by Milledge.

Finish	Surface Roughness Factor, Ra (μm)	Retention of Sucrose Solution (grams) 0.46° Inclination	Retention of Sucrose Solution (grams) 3.7° Inclination
Opaque finish mechanical polish	0.25	67	25
Bright finish polish	0.26	31	9
Electropolished surface	0.40	22	7

Table II.

Retention of sucrose observed for the *electropolished* surface was minimal, despite showing a greater degree of rugosity.

Both investigators, Jordan and Milledge, concluded that for purposes of good cleanability, the characteristics of the surface are far more significant and relevant than are the dimensions of any existing abnormalities.

Plant Experiences

In the production field, certain significant, related events have been experienced.

In a paper manufacturing mill in Sweden, after a 22 month operation, it was discovered that the only tubes evidencing no fouling within a tubular evaporator, were tubes that had been electropolished[4].

A similar test was conducted at a Kentucky plant in the United States, where it had been found necessary to shutdown the plant every eighteen (18) batches for purposes of cleaning a heat exchanger. After submitting the tubes to the *electropolishing* process, a record figure was reached: thirty-nine (39) batches were completed without experiencing fouling[5].

In these cases, there were documented savings on various aspects of plant operations such as: reduction of dead time periods, energy, pumping and cleaning operations.

The evident performance advantages of surface cleanability are derived from the fact that, differing from the usual mechanical polishing operation where metal is violently removed, in the *electropolishing* process the metal is smoothly removed by nonmechanical action[6]. In ensuing paragraphs, we shall be able to appreciate another outstanding aspect derived from the above mentioned difference.

Corrosion Resistance

Wulff[7] conducted a minute research study in an attempt to determine exactly what alterations occur in the stainless steel surface when it is mechanically polished. He discovered that abrasive particles, besides tearing off the steel burrs, cause such phenomena as:

- metal spot heating
- stress
- fissures or cracks
- metallographic structure alterations
- adherence of said abrasive particles to surface
- a superficial metallic flow

At the conclusion of such a mechanical operation, one is able to observe at a microscopic level that the subject surface is left in a deplorable condition, thus becoming "an easy prey" to corrosion. On the other hand, the *electropolishing* process removes metal without causing such disturbances, leaves an unaltered smooth and sound steel and conditions the steel surface to a maximum resistance to corrosion.

Wulff's study has been amply verified through experiments conducted by NASA[8], and further by Tajima[9] in over sixty (60) corrosive media. Furthermore, *electropolishing* has not only been known to improve the quality of metal surfaces, it also has proven to be an effective and severe inspector of surfaces[10].

Detection of Weld Pores and Cracks

This quality of *electropolishing* may perhaps account for its low popularity among manufacturers of pharmaceutical equipment. After electropolishing several dozen tanks, a Mexican manufacturing firm specializing in this process encountered an interesting experience. Vessels and containers were all initially submitted to a first class finishing operation worthy of any accredited and prestigious pharmaceutical laboratory. The tanks also were submitted to rigorous "X-ray" inspections, microscopic and profilometrical inspections, and inspections with penetrating liquids (dye check) for detection of pores and cracks. Nevertheless, the vessels showed pores and fissures after being submitted to the *electropolishing* process. *Electropolishing* does not cause pits or cracks. It simply removes the altered and damaged metal layer which is generated by the mechanical polishing, thus disclosing such flaws that the work damaged layer was hiding.

As an example, a container measuring 3.16m diameter by 2.40m height (the interior view of which is shown in Figure 5) showed after being submitted to *electropolishing* nearly 200 pores and cracks. Upon detection of such flaws, it is possible to correct them through welding and mechanical and electrolytical polishing, thus obtaining a final product that can truly be called sanitary equipment.

Figure 5. Electropolished interior surface of a tank. Notice the reflection attained by the process.

Conclusion

The traditional stainless steel sanitary finish consists of a misleading and altered surface, having poor cleanability and poor corrosion resistance. On the other hand, the *electropolished* finish provides the greatest cleaning feasibilities, reveals any flaws and can be used to produce a truly sound and smooth surface with a far greater durability than a conventional sanitary finish because of its increased corrosion resistance.

Through application of the *electropolishing* process, contamination risks may be reduced, and the useful life of pharmaceutical equipment increased.

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