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Vanton Pump & Equipment Corp.
201 Sweetland Avenue
Hillside, NJ 07205 USA
Telephone: 908-688-4216
Fax: 908-686-9314
E-Mail: mkt@vanton.com
www.vanton.com

Vanton Pumps (Europe) Ltd
Unit 4, Royle Park
Royle Street
Congleton, Cheshire, UK CW12 1JJ
Telephone: 01260 277040
Fax: 01260 280605
www.vantonpump.com

Plastics vs. Stainless Steel... Which is Better?

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By Rich Greene

Pharmaceutical Plants: Choose Your Material

If you've ever opened a faucet at home to find that the water coming out had a brown color, then you know part of the problem —rust from the iron in your pipes. While this is bothersome at home, it is unacceptable at a pharmaceutical plant, particularly in a purified-water line.

Pharmaceutical plants have been traditionally using Type 316L stainless steel (SS) as the preferred material-of-construction. Since Type 316L SS contains about 70% iron, it can rust under aggressive conditions. (The "L" is for low carbon (< 0.03%), needed to help prevent intergranular attack.) In high-purity water systems, deposits on stainless surfaces are thin and are referred to as "rouge" due to their reddish-brown hue. However, rouge is only part of the problem. One way to eliminate rouge is by using plastics instead of stainless steel.

Selecting the most suitable material of construction for pharmaceutical pipes, equipment and other systems is a complex issue that has aroused debate among those in the pharmaceutical community. To help clarify this issue, the New Jersey section of the International Society of Pharmaceutical Engineers (ISPE; Tampa, FL; www.ispe.org) held a forum on plastics vs. stainless steel at its meeting in Somerset, NJ (June 11, 2002). "Choosing the optimum material is far from easy," says George Black, a communications consultant who organized the forum. "A similar problem was faced by the semiconductor industry more than 10 years ago. The decision that pharmaceutical companies must make is more complex," he says.

For instance, the water-quality standards required for the process fluids used in the manufacture of sophisticated electronic equipment could readily be judged by performance-testing the units. "With performance as the judgment criterion, the increased benefits offered by the thermoplastic materials were easy to evaluate and justify in terms of quality and cost," says Black. "Plastics won this battle because they proved cost-effective and met or exceeded equipment test standards." The effect of impurities in pharmaceutical water is another story. Every change in the manufacturing procedure or equipment that might affect the purity of water for ingestion or injection in a human being has to be validated before use. This validation requires extensive testing beyond chemical analysis.

Designers of pharmaceutical and biotechnology manufacturing and processing systems must overcome more than just a natural resistance to change. They need to address problems such as getting internal-management approval, justifying capital costs involved in making the change, securing validation, and dealing with the potential liability, if these changes affect the health of their customers. As Shakespeare so aptly put it, "There's the rub."

Will the pharmaceutical industry do what the semiconductor

manufacturers did — and switch to plastics? The choice will depend on the material's ability to resist leaching, withstand heat, and show good structural integrity. But by far, the key issue is avoiding contamination (see the sidebar).

FORESTALLING ROUGE

The culprits behind rouge are dissolved iron and oxygen. Elemental iron (Fe^{+2}) is insoluble in water, but oxygen converts it into Fe^{+3}, which precipitates as either Fe_2O_3 or $Fe(OH)_3$. One gram of iron will cover an area of 65 x 65 ft^2 (6.04 m^2 x 6.04 m^2), three atoms deep. This is a huge surface. Oxygen can enter a system through seals, such as on a pump impeller or by diffusion through plastics, which are permeable to gases.

Rouging in water-for-injection (WFI) systems can occur due to active corrosion, such as on non-stainless steel components. But far more frequently, rouging results from simple oxidation of trace quantities of dissolved iron. Engineers who are familiar with water treatment will recognize this as aeration. "It may be far easier to prevent aeration and the resulting precipitation than to eliminate trace iron from process streams and systems," says ISPE forum speaker David O'Donnell, manager, technical services, for Rath Manufacturing Co. (Janesville, WI; www.rathmfg.com). "While plastics certainly are iron-free, if there are other components somewhere in a system that are made of steel, there still can be a problem," he says. "Even some 'high-end' plastics are actually permeable to gases (e.g. O_2, N_2, He, H_2, CO_2) and many solvents. It is this permeability that leads over time to blistering behind plastic-lined items," says O'Donnell.

In general, there are three types of rouge. Type 1 is due to the dissolution of steel, such as is found on a pump impeller. Type 2 results from active corrosion and Type 3 is due to high temperatures. Passivation is a technique commonly used by pharmaceutical companies to rid a system of rouge. "Passivation cleans out rouge, but it doesn't prevent Types 1 and 3 from happening again. If oxygen permeates the system, rouging can recur," says O'Donnell.

Type 2 is often the result of improper welding techniques that leave a heat-affected zone (HAZ) near the weld. Type 2 rouge strikes the HAZ, not the weld itself. "During fabrication, manual field welding should not be allowed," says O'Donnell. "Use automatic orbital welding whenever possible to prevent heat tints from forming. Follow this with post-passivation acid treatment and then neutralize with an alkaline rinse," he recommended.

The 300 series stainless steels are sensitive to chlorides at a pH of 6.5-8 and at temperatures less than 140°F (60°C). Although Type 316L tolerates about 1,000 mg/L of chlorides, care must be taken in wet-dry zones, where concentrations can reach 26,000 ppm in the worst case (for magnesium chloride).

Still, stainless steel hasn't become the historic material-of-choice because it presents problems. It does have numerous positive attributes. It is impermeable to oxygen, other gases and solvents. It has 10 times the thermal conductivity of plastics, which makes it well suited for heat-transfer surfaces. Stainless steel is strong, too. Its yield and tensile stresses are at least 10 times those of thermoplastics, and it requires about 800°F (427°C) to initiate creep. Many plastics creep at

room temperature. Therefore, plastic piping must be supported properly to ensure its integrity. Steel pressure ratings are generally 20 times higher than those for plastic. "In practice, a 1 in. O.D. 300-series stainless-steel pipe can withstand 1,600 psi (11,032 kPa), while a similar plastic pipe can tolerate a maximum pressure of 75 psig (5.17 bar), but only at room temperature. At 200°F (93°C), plastic loses half of its strength," says O'Donnell.

PROPERTIES OF PLASTICS VARY

While Type 316L has basically one set of properties, those of plastics vary from type to type. Improved properties generally come at a price, so the less-costly plastics, such as polyvinyl chloride (PVC) and polypropylene (PP), generally do not perform as well as the fluoropolymers, namely polyvinylidene fluoride (PVDF), Type 316L's main competitor in pure-water systems. PVDF melts at 352°F (178°C), allowing it to be steam-sterilized, but rigid PVC starts to decompose near the boiling point of water, making sterilization possible only by chemical means. "PVC and PP must be sterilized with hydrogen peroxide or chlorine, which both require a rinse afterward. PVDF not only tolerates steam, but also withstands sterilization by ozone. Ozone has a half-life that is measured in minutes, so no post-sterilization cleaning is needed," says Gary Dennis, worldwide market manager, technical polymers for Atofina Chemicals (Philadelphia, PA; www.atofina.com). Still, PVC and PP are inexpensive and are common in chemical process industries (CPI) plants.

COST VS. PERFORMANCE

Fluoropolymers are available that can outperform PVDF in temperature resistance, such as perfluoroalkoxy (PFA) resin, which can be used at operating temperatures to 500°F (260°C). But these formulations are expensive and usually exceed the needs of a pharmaceutical plant. "PVDF is among the hardest fluoropolymers and has among the highest tensile strength in this family of plastics. It even has better abrasion resistance, often referred to as particulation, than stainless steel," says Dennis. Particulation is measured by the amount of polymer abraded from a surface by a rotating wheel. PVDF's particulation is 5-10 mg/1,000 cycles of rotation, while that for SS is about 50 mg/1,000 cycles.

Fluoropolymers have excellent chemical resistance including to deionized water, high thermal stability and they resist degradation by sunlight. Also, since they have low coefficients of slip, microorganisms (notably, fungi and bacteria) generally do not grow on them. On the contrary, metal surfaces cannot easily be smoothed out to a degree that can compete with plastics. Microbial-induced corrosion (MIC) is not uncommon in chemical plants, (i.e., in heat exchangers), and can take place on micropolished stainless-steel surfaces in pharmaceutical facilities. In chemical plants, biocides can be added to process water to prevent MIC in cooling towers and heat exchangers. Not so in an ultrapure water system.

Although quite smooth, polymer surfaces can contain molecules that can leach out into water streams. In its virgin form, PVDF is highly pure and contains no additives. Thus, nothing will leach out. But polymers

such as PVC and PP can have additives. These include plasticizers, heat stabilizers and flame retardants.

PVDF, however, is not an inexpensive plastic, but piping and vessels fabricated out of it, or lined with it, are said to be about 10% cheaper than comparable all-stainless systems. Although neither material (PVDF or stainless steel) is perfect, each has substantial advantages and proven track records in pharmaceutical plants, as well as in other CPI installations. "Since pharmaceutical plants traditionally use stainless steel, switching to plastics isn't going to be easy," says Black. But the switch may be on.

"Eventually, the semiconductor industry embraced the high purity and corrosion-resistance advantages of plastics. It is only a matter of time before the pharmaceutical industry follows suit," says Rick Bolger, marketing manager for Plast-O-Matic Valves (Cedar Grove, NJ; www.plastomatic.com). Obviously, some applications will forever be stainless steel, due to high-pressure and temperature considerations. But for many applications, change is inevitable. "We find that interest is growing for thermoplastics in the pharmaceutical community, particularly for homopolymer PP and a number of fluoropolymers, including PVDF," says Bolger.

The debate will result in an education process on both sides: The plastic piping industry has historically been geared toward the needs of the core CPI segments and toward semiconductor manufacturers. "These needs don't necessarily apply to pharmaceutical industries," says Bolger. "It's likely that some new products will arise as a result." By the same token, the pharmaceutical engineer will need to learn how to design a plastic system, including understanding the materials and the numerous joining techniques available. The plastic piping industry is positioned to solve contamination problems, and the pharmaceutical engineer is geared toward improving quality and efficiency, so plastics may make further inroads into this area. Some companies have had plastic pure-water systems in-place, and have already found success with them (see the above sidebar).

PLASTICS VS. STAINLESS: THE DEBATE GOES ON

PRO-PLASTICS

"The question has been raised as to the suitability of sealless, magnetically-coupled pumps for use in pharmaceutical and other high-purity water systems. The reason for concern is the potential for bacteria formation in the gap between the inner magnet and the containment can. This gap is frequently less than 0.03 in. Current thermoplastic mag-drive designs, however, offer clearances of 0.09-0.10 in. Further, they provide wide, open fluid passages for the continuous flow of fresh liquid, as well as drain plugs to assure complete clearing of the passages within the pump and in the suction piping back to the shutoff valve." —Dan Besic, chief engineer, Vanton Pump & Equipment Corp. (Hillside, NJ), 2001 technical seminar.

PVDF and PP plastic systems are inherently superior to stainless steel in that they are manufactured from 100 % pure resin. Unlike stainless steel alloys, there is virtually no difference in the chemical composition of manufactured lots of material. The welding process or chemical cleaning procedures do not degrade the corrosion resistance of thermoplastic systems." —Roger Govaert, Asahi/America, and Albert Leughamer AGRU Kunstsofftechnik, in Ultrapure Water, Dec. 2001.

PRO-STAINLESS

"Both plastics and metal have logical industrial applications. Metals are favored for larger, industrial systems operating at higher temperatures. Under these conditions stainless steels and the higher alloys make a lot of sense.

"Plastics have very low strength and temperature tolerance relative to metals. Many WFI systems operate at 180°F (82°C) and use steam cleaning protocols. Metals tolerate steam cleaning with no difficulty. Plastics typically soften considerably at such temperatures.

"WFI systems should be designed to minimize oxygen to avoid this. Avoiding the use of plastics would be one key step, as plastics are permeable to oxygen. The use of nitrogen blanketing in accumulation tanks would be another step, as would the use of magnetically-coupled pumps (no rotating shaft seals exposed to process steam).

"Metals have no significant flow limitations. Plastics suppliers often use 10-12 ft/s (3.048 - 4.587 m/s) as a maximum flow speed, particularly on plastic-lined items to avoid damage." —Dave O'Donnell, manager, technical services, Rath Manufacturing Co. (Janesville, WI)

AN EXISTING PVDF INSTALLATION

As evidence of the possible wave of the future, Christ, Ltd. built a purified water-treatment plant and distribution system for Sulzer Orthopedics in Winterthur, Switzerland. The plant has been in operation since 1966. Christ was awarded the contract because it had successfully built similar pharmaceutical facilities requiring purified water that met European Pharmacopoeia and other guidelines on sterile products. High requirements were set in regard to the distribution system. Design factors included:

- No deadspaces within the system
- Low surface roughness of piping material and welding seams
- Dynamic operation of the system with a high velocity
- Periodic disinfection with ozone.

The complete distribution loop was installed using bead- and crevice-free, high-purity PVDF piping. The pure-water plant easily and continuously meets the requirements set by Sulzer Orthopedics in regard to conductivity, capacity and yield, and the water-purity quality meets and surpasses the requirements set by United States Pharmacopeia (USP). For example, the target conductivity for the water was set at $<10\ \mu$S/cm and the plant's diluate is below detection limits. The chloride target was 5.3 ppm, and, it too is below detection limits.