Design Parameters for Pharmaceutical Storage Vessels Require the Consideration of...

Vessel Volume: Determined by client requirements, but also diameter and straight side dimensions selected for optimal costs (material quantity).

Pressure Rating: 45 psig (for steam sterilization) and full vacuum or vacuum protected (for pump out or condensing steam); ASME code construction and stamp; sterile vent sizing.

Corrosion Resistance: Material selection and surface finishes for high resistivity water usually at an elevated temperature.

Temperature Maintenance: Heat transfer jacket or external heat exchanger; properly sized and installed insulation.

Sanitary Components: Pressure and level transmitter connections; nozzles, manhole, CIP connections, thermowells, etc.

Quality: Overall construction and appearance including welds and finishes.

DCI can provide criteria for evaluating materials, surface finishes, insulation, and overall design and construction of pharmaceutical storage vessels.
**MATERIAL SELECTION**

Chemical resistance tables may give the impression that any of the stainless steel alloys will be suitable for use with distilled/deionized water, but such charts ignore the fact that the materials must be formed, machined, polished or welded. Once finished components are subjected to high temperature applications, it is possible to observe distinct differences in performance.

Accelerated testing studies have shown, for example, that type 316 stainless steel has better corrosion resistance than type 304 stainless in the presence of high-purity water. The use of type 316L (low carbon)-grade stainless exhibits better corrosion resistance at the weld area by reducing the risk of formation of chromium carbide precipitates. The precipitated chromium carbides are discrete inclusions that affect the continuity and stability of the passive surface film which renders the material resistant to attack.

However, the specification of type 316L stainless is not all that is required for material selection. Since there is a wide variation in the elemental and purity level of type 316L stainless, care needs to be exercised in the selection of the actual material used. Consideration should be given to the use of a high purity type 316L stainless (electro-slag removal process).

**PRODUCT CONTACT SURFACE FINISHES**

Mechanically polished surfaces with No. 150, 180, etc. grit finishes are often specified for pharmaceutical vessels because the mechanical finishing will generally reveal pits and other defects in the basic material. The grit size is commonly used as a measure of surface roughness (the greater the number, the smoother the surface). In addition, a combination of mechanical and electropolished finish can be specified for a smoother and more corrosion-resistant surface.

**CONSTRUCTION SELECTION**

Compatible materials should be used throughout for pharmaceutical vessel construction including CIP and instrument connections, nozzles, and manway. Heat transfer surface placed on a vessel should also be compatible and properly sized to keep costs to a minimum and eliminate control problems. Consideration to the application of a heat-resistant silicone barrier coating and to the use of chloride-free insulation should be given to reduce the risk of chloride-induced stress corrosion and pitting. Sheathing of type 304 stainless steel over the insulation is often specified because it is attractive and virtually maintenance-free.

**FABRICATOR SELECTION**

The fabricator selected for the construction of a water storage vessel should be experienced in supplying equipment to the pharmaceutical industry. More importantly, the fabricator should have the technical personnel that understands material selection, vessel design and the quality craftsmen and control personnel to provide your desired finished product.