THE ADVANTAGES OF TANTALUM AND NICKEL-BASED ALLOY SHELL AND TUBE HEAT EXCHANGERS vs. CARBON BLOCK HEAT EXCHANGERS IN PHARMACEUTICAL API APPLICATIONS

By: Lawrence J. Haubner – TITAN METAL FABRICATORS/2011

About The Author:
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The pharmaceutical industry has traditionally used resin-impregnated graphite block heat exchangers for handling corrosive fluids in their active pharmaceutical ingredient (API) manufacturing facilities. During the past three decades, tantalum and high nickel alloy shell and tube condensers have emerged as a versatile alternative offering superior corrosion resistance that are commonly used by the world's leading pharmaceutical manufacturers and pharmaceutical engineering companies including:

- ***Abbott Laboratories***
- ***Aker Solutions***
- ***Astellas Pharma***
- ***AstraZeneca***
- ***Avecia***
- ***Aventis Pharmaceuticals***
- ***Baxter***
- ***Bayer Corporation***
- ***Boehringer Ingelheim***
- ***Bristol Meyers Squibb***
- ***Clariant***
- ***CHM2Hill***
- ***Covidien***
- ***Eli Lilly & Co***
- ***Glaxo SmithKline***
- ***Hoffman LaRoche***
- ***Jacobs Engineering***
- ***Janssen Pharma***
- ***Merck & Co.***
- ***Noramco***
- ***Novartis***
- ***Pfizer***
- ***Pharmacore***
- ***Schering Plough***

Tantalum and Hastelloy eliminate most problems associated with the use of graphite for pharmaceutical processing; their advantages include:

- ***No production downtime for repairs and replacements***
- ***Purity of the pharmaceutical end product***
- ***Faster, validated clean-out between batches***
- ***Superior corrosion resistance***
- ***The ability to process any pharmaceutical product while meeting the strictest regulatory standards***
- ***Elimination of cross contamination of heat transfer fluid into the process due to gasket leaks or broken graphite blocks***

TANTALUM PHARMACEUTICAL CONDENSERS INSTALLED WITH GLASS LINED STEEL REACTORS

Corrosion Resistance

A naturally-occurring oxide film on tantalum's surface makes it resistant to corrosion in even the most severe acid environments and completely resistant to organic compounds. This superior corrosion resistance makes it suitable for any application within the pharmaceutical industry, particularly when corrosive chlorinated organics are involved at elevated temperatures and under vacuum conditions. Tantalum is inert to most organic and inorganic compounds at temperatures up to 450° F. It is inert to sulfuric acid below 300°F and the attack below 400° F is not significant. Tantalum is also inert to hydrochloric acid in all concentrations and at all temperatures up to 350° F. The corrosion resistance of tantalum is virtually identical to that of glass making it the perfect complement to glass lined reactor systems.

The corrosion resistance of nickel-based alloys results from a high nickel and molybdenum content. These alloys are known to corrode slowly and predictably. While the corrosion resistance of nickel based alloys is not as high

as tantalum there are many applications where it can be used with satisfactory corrosion resistance and all of the advantages of that of tantalum with a reduced cost to the end user.

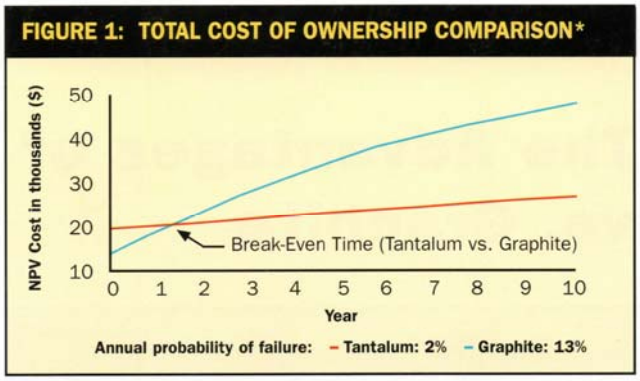
THE ADVANTAGES OF TANTALUM AND NICKEL BASED ALLOY CONDENSERS

No Production Downtime

Metal tube condensers are exceptionally durable and will perform for many years without any lost production time for repairs or replacements. The long service life of a metal tube condenser provides the highest productivity rate while eliminating maintenance costs and replacement expenditures.

In contrast, graphite is susceptible to mechanical damage, with breakdowns commonly occurring during handling, installation, operation and cleaning. The greater failure rate of graphite systems necessitates frequent repairs and replacements, resulting in lower productivity and higher maintenance costs.

Metal tube condensers require a larger initial investment than graphite condensers. However, because production downtime translates into asset depreciation, higher operating costs, and lost sales due to longer time to market, the break-even time for tantalum versus graphite is only 18 months. (See Figure 1)



*Courtesy of L.J.R. Cohen and R.C. Young, Zeneca Engineering, Manchester, U.K.

Moreover, long-term cost comparisons demonstrate that despite higher capital costs, metal tube condensers are more economical than graphite, due to its greater durability and longevity.

Product Purity

Pharmaceutical product purity is mandated by stringent regulations at the federal, state, and local levels. But resin-impregnated graphite often fails to meet the industry's quality control requirements. As the impregnated graphite surface heats up and cools down, the difference between the thermal expansion rates of graphite and the phenolic (or Teflon) impregnate creates stress. This stress causes erosion at the graphite surface in the same way that water's freeze-thaw cycle erodes a concrete surface. As a result, minute graphite particles and resins flake into the process batch, contaminating the end product.

TANTALUM PHARMACEUTICAL CONDENSER WITH 316L STAINLESS STEEL SHELL

Faster, Validated Clean-Out

All condensers must be thoroughly flushed between process batches to satisfy good Manufacturing Practice (GMP) procedures as well as regulatory standards. Clean-out is extremely difficult and time-consuming with impregnated graphite, because graphite's rough, porous surface absorbs both the process fluid and the end product.

With its smoother surface, metal tube condensers can be flushed much more quickly, resulting in dramatic cost savings and increased productivity. The clean-out procedure can also be validated easily by opening the tantalum condenser for inspection, which is not possible with the design of a graphite condenser.

No Leakage / Cross Contamination

When low surface-tension heat-transfer fluids such as Syltherm™ and Dowtherm™ J are used in place of cooling water, tantalum prevents leakage, while graphite creates problems. The graphite block design of multiple gaskets and a floating-head dynamic seal cannot provide an effective closure. In some cases shellside fluid has been known to permeate the graphite block itself.

High Thermal Efficiency

The relatively thin walls of metal tube condensers transfer heat more effectively than the thicker walls of cross bored graphite blocks. In many cases, tantalum condensers have been shown to require 40 percent less heat transfer surface area than impregnated graphite exchangers for the same application. Tantalum condensers can be thermally-sized to precise specifications for any application to reduce the surface area and minimize the required spacing.

Universal Versatility

Because it is versatile enough to process any pharmaceutical product, tantalum and Hastelloy can be fabricated into universal systems to meet any production requirement, as well as the most exacting regulatory standards. Therefore capital-equipment decisions can be made more efficiently and new pharmaceutical products can reach the market without delay to maximize profits.

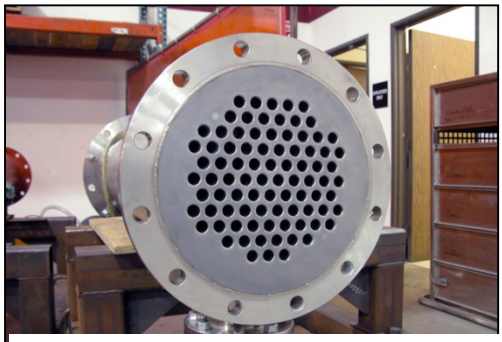
FABRICATION FEATURES

TITAN Metal Fabricators, Inc. has developed high-quality processes and designs to serve the specialized needs of the pharmaceutical industry.

These design features include:

Leak Detection – Tantalum tubesheet and bonnet designs can include ports that allow leakage past a tube sheet weld to be diverted to a collection system outside the condenser. In addition to early leak detection, this design minimizes contam coolant by the pro

TANTALUM, HASTELLOY C AND 316L STAINLESS STEEL PHARMACEUTICAL CONDENSER WITH CIP SPRAY BALLS



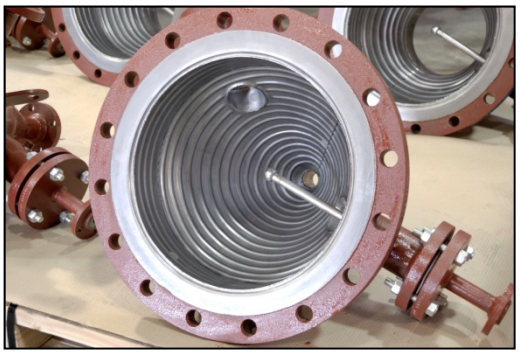
TANTALUM CONDENSER WITH FLUSH FACE TUBESHEET TO ENSURE FULL DRAINABILITY

Complete Drainability –Tube sheet and bonnet designs and welding processes can minimize the ability of the tube sheet area to retain fluids during draining and cleaning.

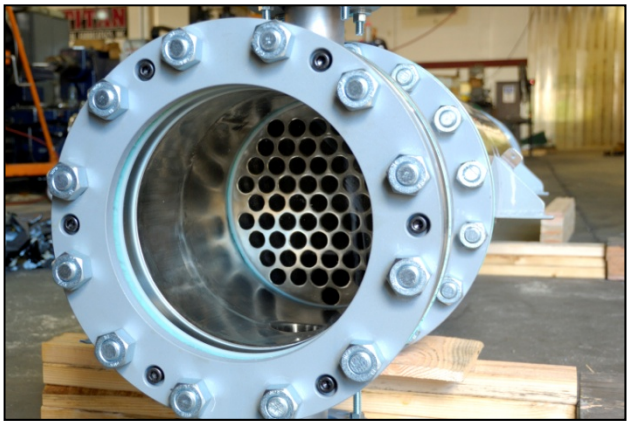
Polishing Of Metal Condensers – Tantalum mill products that are used in tantalum pharmaceutical condenser is offered as a standard as a minimum of 20 Ra surface finish. This typically exceeds the required surface finish of a condenser for this service. Hastelloy condensers can be offered in a variety of surface finish from standard mill finish to an electro-polished surface of approximately 10 Ra.

CIP Cleaning Devices – CIP (Clean In Place) spray devices can be installed to ensure fast thorough cleaning of the process side of the condenser.

Riboflavin Testing – All CIP spray devices applied into these condensers can be riboflavin tested to ensure that the CIP spray device is adequately cleaning the process side of the condenser.



TANTALUM CONDENSER WITH CIP SPRAY BALLS FOR CLEAN IN PLACE

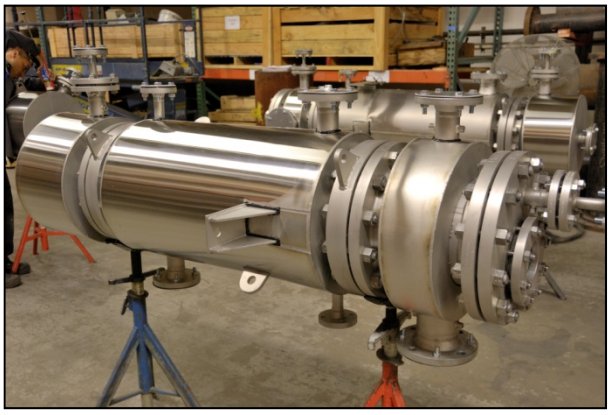


ALLOY C CONDENSER WITH TUBESIDE POLISHED TO 20 RA AND SIGHT GLASSES ON BONNET FOR VIEWING CONDENSATION

Sight Glasses for viewing of condensation / verification of cleaning – The mechanical design of a metal shell and tube heat exchanger allows for the application of site glasses on the bonnets for viewing of condensation performance as well as the positive verification of the cleaning in between each batch.

Integral Insulation – Polished stainless steel sheathed insulation can be applied to our condenser at our facility to save time during installation.

Silver brazing – All tantalum linings are silver-brazed to the carbon steel substrate to prevent contamination and gasket leakage.



TANTALUM CONDENSER WITH INTERGRAL INSULATION, SIGHT GLASS, AND CIP SPRAY BALLS

COST EFFECTIVE

Despite higher capital investment costs, tantalum and Hastelloy condensers have consistently proven themselves to be more cost effective than graphite. Tantalum and Hastelloy condensers are virtually maintenance-free, providing long-term durability and faster validated clean-out. Life-cycle cost studies have shown that the payback time for tantalum can be less than two years.

References:

Tantalum and Niobium Materials for the Pharmaceutical Industry – Mike Coscia / HC Starck
Materials Selection Issues for Heat Exchangers in the Pharmaceutical Industry – LJR Cohen / RC Young / AstraZeneca
Teflon is a registered trademark of E.I.DuPont de Nemours and Company
Syltherm and Dowtherm™are trademarks of Dow Corning Corporation
American Society for Metals – Properties and Selection – Non Ferrous Alloys and Pure Metals, 1979
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FEATURES OF A TITAN TANTALUM PHARMACEUTICAL CONDENSER