

The Magazine For Pump Users Worldwide

PUMPS & SYSTEMS[®]

Selecting a Sanitary Mixer Seal for Pharmaceutical Applications

Originally published
November 2008



Reprinted with permission from Pumps & Systems Magazine solely for inclusion in the A.W. Chesterton Company Media Kit. Distribution in any other manner or for any other purpose is prohibited.

Selecting a Sanitary Mixer Seal for Pharmaceutical Applications

Christopher Little, A.W. Chesterton

A look at sanitary mixer seal technology including clean ability, drain ability, material compliance, contamination and advancements.

Given public health concerns, the pharmaceutical industry must carefully choose sealing process equipment, particularly for cleaning and sterilization processes. Fortunately, internationally recognized organizations regulate and publish guidelines for specific seal design attributes, material requirements and mechanical seal selection for pharmaceutical manufacturing equipment. These organizations frequently conduct committee meetings of equipment manufacturers, users and consultants to review industry best practices and acknowledge the latest technological advancements. It is their goal to ensure that industry professionals are aware of the safest and most commercial viable techniques.

This article will outline some of those major specifications related to mechanical sealing in pharmaceutical processing equipment.

Clean Ability

In the seal selection process, users want to know that the seal can be sterilized through Steam-in-Place (SIP) or cleaned through a Clean-in-Place (CIP) operation. They need a design that will accommodate these processes and rid bio-burden growth or contamination.

Clean ability is best accomplished through some basic design considerations. All wetted metal components must

have a smooth surface finish that minimizes roughness and avoids irregularities that would otherwise tend to capture process fluids and reduce cleaning fluid effectiveness. The normal requirement for wetted process surfaces is 15-20 Ra. This finish is less likely to capture contaminants or allow materials to adhere to the surface. A typical machined surface on a standard mechanical seal is 32-63 Ra. These better finishes are achieved through various electro-polishing or mechanical-polishing techniques.

Another physical design consideration is minimized crevices. O-ring grooves, NPT threads and metal-to-metal surfaces inherently produce crevices. O-ring grooves, static or dynamic, are typically modified where the clearances are enlarged to allow cleaning fluids (CIP) or steam (SIP) to access the area and clean/sterilize successfully. The seal designer must not promote O-ring extrusion or inhibit sealing ability under vacuum or pressure conditions. The preferred method of sealing metal-to-metal parts is with a conventional O-ring groove design, rather than a flat gasket, i.e., how a seal is attached to a vessel nozzle. Internal threads can be isolated or eliminated from the process by using either static O-ring seals or hygienic fittings respectively.

Drain Ability

Drain ability means process materials and cleaning materials,

including water and steam, can successfully drain from dead spaces and crevices without pooling. *Pooling* occurs when a fluid remains after the cleaning process, which encourages contamination, especially in a batch type process, and compromises the cleaning or sterilization. Drain ability is often a concern in vertical applications where crevices are more likely to form, e.g., O-ring grooves or flat areas. Users should look for designs that employ continuous sloped surfaces and avoid surfaces that may act like a “shelf,” which can cause pooling on that surface. In theory, a sterilized drying process should eliminate residual moisture.

Another design attribute that should be avoided are *dead legs*, areas where continuous circulation or drainage cannot take place. Dead legs can also promote pooling. For example, a gland flush port used for cleaning should be angled such that any cleaning solution or process fluid, including water and steam, can successfully drain.

Material Compliance

Material selection is an important component to selecting a seal for use in sanitary pharmaceutical applications. Generally, 316L stainless steels or higher grade materials such as AL6XN and 2205 are acceptable. Non-metallic materials must be biocompatible and carry compliance documentation. The seal user must specify the material requirements for their particular sealing application. First, materials must be compatible with various cleaning solutions (CIP) and sterilization high temperature steam (SIP). Materials must also be biocompatible, which protects the health of the general public by ensuring that the process fluid is not adversely affected by the seal materials.

Two popular governing bodies responsible for specifying seal materials are the Food & Drug Administration (FDA) and United States Pharmacopeia (USP). A supplier of FDA materials can verify that the materials used in their design meet FDA requirements as per 21 CFR 177 standard governed by the FDA.

Materials not covered under 21 CFR 177 and potentially contacting products shall be tested for extractables under USP <661> or <381>. Extractable results shall be available upon user request. Additionally, certificates of compliance may be required under the USP directive with regard to USP <87> and USP Class VI <88> on biological reactivity. This requirement is substantially different from 21 CFR 177 because the manufacturer of the seal and the seal materials must be able to produce certificates of compliance for traceability purposes. The documentation certifies that the material was tested by a third party laboratory meeting the toxicology requirements under in-vitro and in-vivo testing guidelines.

Seal Contamination

Contamination comes from external and internal sources. This article will focus on contamination from the sealing element, or the internal process. One contaminant that concerns most users is carbon dust entering the process. A single mechanical seal

design typically uses one hard face—ceramic and one carbon soft face. Contacting end face seals will emit carbon dust while in operation because the carbon is a sacrificial, wearing surface.

The single seal arrangement depends on the graphite in the carbon structure to provide lubrication to the seal faces. This carbon graphite is important in both liquid film regimes and dry run environments. Dry run will naturally produce higher wear and emit more carbon than a liquid lubricated seal. Hard face-to-hard face designs can be used as a means to minimize the carbon wear, but this is limited to very low speeds or liquid film regimes. Most often, dry run is not an option with hard faces, unless more exotic seal materials or elaborate seal designs can be used.

Historically, the solution to minimizing carbon ingestion in a dry run vertical application is a debris well, also known as a sanitary gland. This added feature is a labyrinth installed between a seal and the equipment for which it is mounted (see Figure 1). This debris well will be cleaned with a CIP solution or an SIP process utilizing the required clean-out ports. The debris well must be drainable.

Dual seals provide a backup seal, which keeps air and atmospheric contaminants out of the process when vacuum operations are involved and allows planned maintenance if an inboard seal fails. If the inboard seal fails, the process is contained with the secondary (outboard) seal. A dual seal will also minimize the carbon ingestion. By design, the dual seal provides a barrier/buffer environment providing lubrication to the seal faces, ultimately minimizing or eliminating carbon dust. Typically, the soft carbon face is replaced with a hard face to produce a hard face-to-hard face combination. Particle ingestion is virtually eliminated when a dual seal is operated with hard faces and a barrier/buffer environment (see Figure 2).

Unfortunately, the support systems associated with dual sealing can also introduce process contamination if the inboard seal fails. For this reason, most pharmaceutical manufacturers

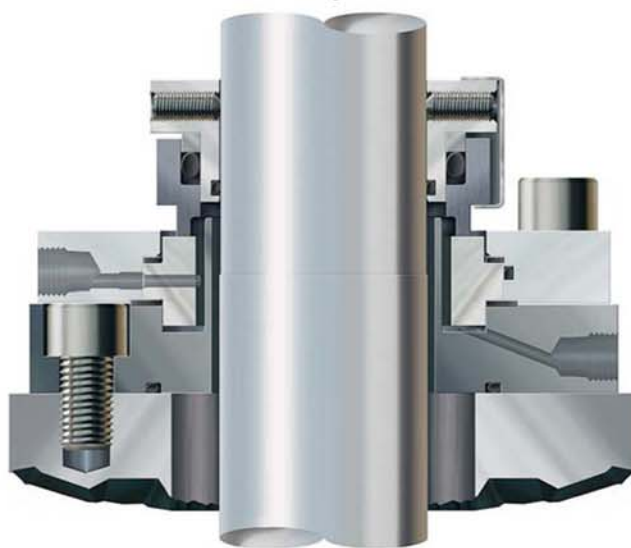


Figure 1

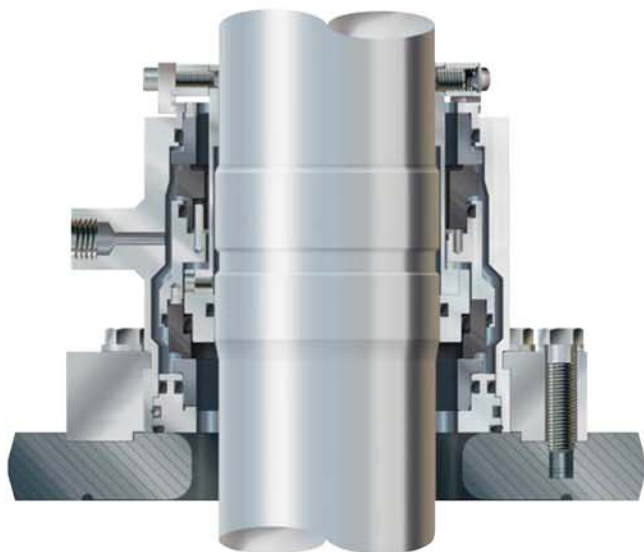


Figure 2

use a fluid that is compatible with their process, i.e., mineral oil or glycerin. Hard-face to hard-face combinations are used because it is almost guaranteed the seal will leak when carbon is combined with an oil environment. In the event of a seal failure, the user may justify the mixing of this barrier/buffer fluid with the process because it is compatible and not deemed a contaminant.

Due to the need for sterilizing, which is always addressed through CIP and SIP, this compatible barrier/buffer concept comes with an additional operational requirement. The barrier/

buffer oils must be heated to greater than 230-deg F (110-deg C) to ensure the seal and its support system are sterilized. This operation prevents bioburden growth and contamination within the seal cavity.

This oil sterilization comes with serious disadvantages. First, it is another costly operation in the process. The oil barrier/buffer will need to be directed through oil heaters and filters. It also creates a potential safety issue since it requires the handling of hot oils. With small leaks, hot oils can catch fire and burn personnel.

Gas seals are becoming a popular alternative. Contacting or non-contacting gas seals can reduce carbon ingestion and eliminate the need for hot barrier/buffer fluids required for liquid dual seal operation. Contacting gas seals are lightly loaded and use a sterilized gas to lubricate the seal faces. Wear is still expected but reduced. Non-contacting gas seals also use a sterilized gas to establish seal face "lift-off," further reducing seal face degradation. The only disadvantage to these advanced seal designs is they can be more complicated and require elaborate support systems.

Conclusion

Today's technology has still not perfected reduced contamination sources from mechanical seals. In sanitary pharmaceutical applications, gas seals and "carbon free" seal technologies are becoming more common. New technologies and sealing methodologies are needed to address additional pharmaceutical concerns.

In cleaner sealing or "carbon free technology," non-wearing, high strength non-toxic polymer materials are used instead of conventional seal faces. These designs incorporate a lip type attribute with "carbon free" dry run capabilities. The technology can even tolerate high motion typically found in vessel sealing (see Figure 3).

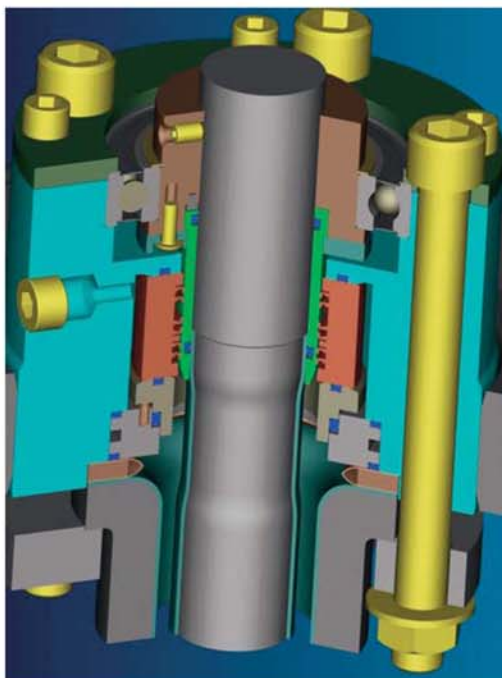


Figure 3

P&S

Christopher Little is the business development manager of mechanical seals for A.W. Chesterton, Phone: 978-469-6554, Fax: 781-481-7411, littlec@chesterton.com.