Effect of dry-running conditions on magnetically driven agitators in bioprocessing

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ABSTRACT The most common purpose of agitation in biopharmaceutical processing is liquid/liquid and solid/liquid blend (solutions and suspensions). Agitators are performing their duty while submerged in a fluid phase, and consequently designed for this intended use, considering that running in air would not fit any purpose. However, when dealing with partly manually controlled standard operating procedures (SOPs), or due to different sequences alternating process fluids with clean-in-place (CIP) and steam-in-place (SIP), combined with a relatively basic automation, the risk of having an agitator running without liquid is present. In the case of top entry agitators, this may not constitute a condition that could damage the equipment. For bottom entry agitators, the situation may be more complex and may result in damage to mechanical seals, or bearings (in the case of magnetically driven agitators) that rely on the process fluids for lubrication. This article discusses what dry-running means when considering magnetically driven agitators, under what conditions this may occur and the potential damage to the agitator, depending on the different bearing designs and materials of construction typically available.

1. INTRODUCTION

Bottom entry magnetically driven agitators feature an impeller that is driven by a magnetic coupling, rather than physically connected to a shaft. This means there is no need to penetrate a process vessel, eliminating mechanical seals and reducing the risk of leaks. By not having a shaft, it is easy to design the process contact surfaces for effective CIP and SIP.

In general, bearings are designed to work with a lubricant. In the case of magnetically driven agitators in bioprocess, the lubricant is the process fluid. This could vary from fluids, such as water for injection (WFI) to final product, as well as CIP detergents and clean steam. The lubricating properties of all these vary greatly. But first, it is important to define what dry-running conditions mean with respect to the bearings.

2. WHAT CONSTITUTES A DRY-RUNNING CONDITION

The only component of a magnetically driven agitator assembly that is susceptible to dry-running is the bearing. Therefore, dry-running conditions need to be seen from the perspective of the bearing assembly surroundings. Dry-running is defined as the absence of a liquid film between bearings. It is not related to the impeller being submerged in fluid or not. A film between bearings can still exists when the vessel is empty, and under some circumstances, may not actually exist in a full vessel. Some example of commonly misunderstood conditions where dry running may occur are listed below:

- Running an agitator while emptying the vessel: in this case, the bearing assembly in the mixer was covered with liquid, and the liquid is drained from the vessel. The bearings would still have a liquid film between them even after the vessel is empty. This liquid film would remain for a certain time that varies with the speed that the agitator is running, the fluid physical properties (specific gravity and viscosity) and temperature. As long as there is still a liquid film between bearings, this is not considered a dry-running condition.
- Running during CIP without submergence: in this case, a spray ball is delivering cleaning solutions and rinse water to the vessel. A properly designed spray ball will aim one or more streams to the impeller head, so that it can be wetted. Like all other surfaces inside

the vessel, any surface that cannot be wetted, cannot be cleaned either. If the mixer speed is kept to the manufacturer's recommendation in this condition, the flow from the spray ball will replenish the liquid film between bearings. This does not constitute a dry-running condition. Often, it is possible that there are a few minutes between the start and stop of each CIP cycle that may lead to some periods of not having flow from the spray ball(s). If the mixer is not stopped in this sequence and runs continuously through the entire cycle, this would be a similar situation as when running the agitator while emptying the vessel. If the lapse in between spray ball flow is too long and, particularly if using hot fluids (e.g. WFI at 80°C), the liquid film may evaporate quicker leading to a dry-running condition.

- Running during SIP: in this case, the vessel is empty. It is uncommon to run mixers during SIP, but it may be necessary to start the mixer for a short interval every now and then to remove condensate. Similar to the CIP condition, as long as the mixer is run per the manufacturer's recommendation for SIP, this also does not constitute dry-running.
- Running without liquid in the vessel for an undetermined time: this may occur if there are no safeguards to stop the mixer once all the liquid has been drained from the vessel. For example, if an operator may forget turning off the mixer and leaves for the day (or even worse, for the weekend), the mixer may be running with no liquid for multiple hours and possibly days. Eventually, the liquid film will evaporate. This is a common situation where dry-running can occur.
- Running the mixer too fast for the volume contained in the vessel: in this case, and when a strong vortex that draws air to the impeller is pulled, it may expose the bearing assembly to air instead of the process liquid and could result in dry-running.

When working with low liquid levels, impeller cavitation is another consideration, due to insufficient net positive suction head. This could also damage the bearings, but it is a different phenomenon that should not be confused with dry-running.

3. BEARING DAMAGE EXPECTED FROM DRY-RUNNING CONDITIONS

According to Folger [5], the number one cause for bearing damage is inadequate lubrication. Therefore, dry-running is an important consideration in terms of bearing failure. Besides the operating conditions (temperature, mixer speed, etc.), the bearing type, specific design and materials of construction will determine how long a bearing can survive dry-running conditions. The range can vary from a few minutes to several days. The one thing that is common in all cases, is that no bearing can survive dry running conditions forever. The most common failure types related to dry-running conditions are described below:

- Bearing fracture: The bearing cracks and breaks into small pieces. If the mixer is not stopped right away, the resulting particles can damage other components in the assembly, such as the impeller and weld-plate. This extended damage is more prominent with materials with high hardness, such as silicon carbide. Bearing fracture is the result of noise generation when the bearings are running dry. The noise will create vibration that will cause the fracture. Brittle materials, such as silicon carbide, are more prompt to this type of failure.
- O-ring damage: During dry-running conditions, surfaces can reach high temperatures due to frictional heating. The amount of heat that is generated will depend on the specific material's coefficient of friction. Materials such as silicon carbide can reach temperatures in excess of 500ºF (260ºC) within minutes. Any O-rings in the bearing assembly will be affected by the temperature and will expand. This expansion could also cause damage to the bearing surfaces, depending on their design. Most O-ring materials will not survive such elevated temperatures and will no longer seal adequately. O-rings are often used to seal the threads between weld-plate and male bearing.
- Increased particle generation: The lack of lubrication during dry-running will contribute to increased particle generation. If the particle generation surpasses the limits imposed by the process, then it is considered that the bearing has failed, even if no fracture has occurred.

4. DESIGN CHARACTERISTICS RELATED TO DRY-RUNNING CAPABILITY

4.1. Bearing design

Most magnetically driven agitators for biopharmaceutical use a journal type bearing. A journal bearing will have a stationary component (male bearing) and a rotating component (female bearing) that is affixed to the impeller. While most designs use the same material for both male and female components, some use dissimilar materials. Unlike mechanical seal stationary and rotating seal faces, the male and female components in a journal bearing are not intended to seal and a small gap between them exists so that the components can be lubricated by the process fluid. In biopharmaceutical applications, this gap is also essential to ensure cleanability and drainability. Therefore, bearing exposure to process fluids during formulation and CIP is important to ensure cleanability and avoid dry-running. For a more detailed discussion of bearing design refer to Steridose white paper *Bearing and magnetic coupling design* [4]

4.2. Materials of construction

Materials of construction play the most important role in the ability of a journal bearing to withstand dry-running conditions. Considering all other variables equal (process fluid, temperature, mixer rpm and bearing design), some significant changes can be seen by just selecting a different material of construction. The way these bearings may fail would also be different depending on the material. Some of the most common bearing materials are summarized in table 1:

Bearing material[a]	Tungsten Carbide	Silicon Carbide	Dri-amond™
Chemical compatibility	pH range 2-14[b]	Best - inert	Same as silicon carbide
Ease of installation and handling	Best	Harder than tungsten carbide, but more brittle	Somewhat better than silicon carbide
Survivability under dry-running conditions	Good	Poor	Best - lowest coefficient of friction

[a] The use of dissimilar materials in male and female bearings is not recommended.
[b] Exact value depends on particular fluid properties, temperature and exposure time.

Table 1 Comparison of bearing materials.

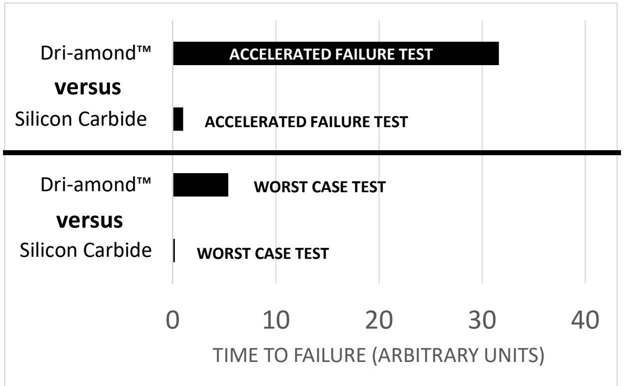

Figure 1 Steridose Dri-amond™ bearings time-to-failure under adverse running conditions versus standard silicon carbide. Refer to the text for descriptions of 'worst case' and 'accelerated failure test'.

When exposed to dry-running conditions, ceramic hard materials, such as silicon carbide, fail due to fractures on the surface. More ductile materials, such as tungsten carbide, do not fracture easily, but may show wear patterns after long periods of dry-running that would provide evidence of an increase in particle generation. Diamond coated silicon carbide would fail in the same way as silicon carbide, but over a much longer dry-running exposure time. The exact time to failure for each material will vary depending on the application conditions. According to Diaccon [7], a diamond coated silicon carbide mechanical seal face could last hours before failure in a dry-running condition, compared to just seconds for uncoated silicon carbide. Advanced Diamond Technologies reports survivability in dry-running conditions of diamond coated silicon carbide mechanical seal faces to be close to 30 times longer than uncoated silicon carbide [8].

Steridose testing of their Dri-amond™ option shows improvement of dry-running capability of journal bearings by up to 30 times compared to uncoated silicon carbide. See figure 1. The worst-case test refers to no liquid film present between the bearing surfaces (parts were installed dry and liquid was never present), while the accelerated failure refers to an initial liquid film present at the onset of the test, with accelerated evaporation (bearings were submerged at first in 90° water and liquid from vessel was allowed to drain completely before starting test).

5. BEARING MATERIAL REQUIREMENTS FOR USE IN BIOPROCESS

According to the latest ASME BPE edition [1], per PM-2.1.3 and table PM-2.2.1-1, bearing materials, such as silicon carbide, tungsten carbide, etc., shall comply with the requirements of USP<87> Biological Reactivity Tests, in Vitro [2] or ISO 10993-5 for biocompatibility. Due to the importance of particle generation in biopharmaceutical processes, most manufacturers also test their bearings in accordance to USP<788> Particulate Matter in Injections [3]. The USP defines maximum particle counts of 25/mL for particles $\geq$10 μm and 3/mL for particles $\geq$25 μm.

6. CONCLUSION

Bearings in magnetically driven agitators are lubricated by the process fluid(s). Therefore, it is important to understand when a dry-running condition may occur. Dry-running is defined as the absence of liquid film between bearings. The bearing design, magnetic coupling design and selection of materials of construction can help increasing survivability of the bearing during dry-running conditions. However, no bearing design can run dry forever. The material of construction can make the most significant difference in the ability to run dry. Ductile materials, such as tungsten carbide, may not be as prone to fracture during dry-running as ceramic materials, such as silicon carbide. Diamond coatings have shown to greatly improve dry-running capabilities in ceramic materials. Materials shall comply with regulatory requirements, such as USP<87> [2] and USP<788> [3].

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