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CLEAN-IN-PLACE (CIP) DESIGN CONSIDERATIONS FOR BOTTOM ENTRY MAGNETICALLY DRIVEN MIXERS

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Introduction

With product contamination being one of the number one concerns in both the biotechnology and pharmaceutical industries, greater demands are being placed on conventional mixer technology. The conventional seals such as mechanical, stuffing boxes and lip seals, which have been around for decades, can only control leakage; they can't prevent it. In some process applications this may be acceptable, but with stricter regulations sealless mixer technology is becoming the preferred choice.

Sealless mixers are mixers without conventional seal technology. There is no mechanical connection between the mixer drive and in-tank impeller assembly. "Connection" is accomplished by magnetically coupling both the mixer drive and impeller while maintaining a hermetically sealed mixing environment. This technology lends itself to mixing applications where potential liabilities in health and safety are a major concern.

With the increase in demand for hermetically sealed mixing, clean-in-place (CIP) design features are becoming a critical component in biopharmaceutical facilities. This paper presents some design considerations used when developing a bottom entry sealless mixer, and specifically looks at different bearing technologies for magnetically driven impellers. This paper also presents results from a CIP protocol comparing the cleanability of two different impeller designs, each utilizing a different bearing technology.

Background

Magnetically driven bottom entry mixers have been used in industrial applications for more than 15 years, but have become more popular in recent years because of the advantages they bring to the biopharmaceutical industry. The one key advantage, and the main topic of this paper, is the ability to CIP the tank contents (which include the impeller) while keeping the contents hermetically sealed to the outside environment. With this key advantage, a great deal of concern is placed on the CIP design features incorporated in the magnetic impeller design. As with all products, some magnetic mixer designs are more cleanable than others. As with any new product design it is the manufacturers responsibility to evaluate the cleanability and ability to remove residues during a CIP process. This paper will specifically look a the most critical area to clean on a magnetic impeller assembly, the bearing, and will also compare the cleanability of different bearing designs.

Bottom Entry Sealless Mixer Design

Magnetic Coupling

Bottom entering magnetically driven mixers, regardless of the magnetic coupling design, transmit torque with a magnetic field. Depending on the torque requirement, the same number of magnets (each being a pole) are assembled in both the impeller and magnetic driven assemblies. When the mixer is fully assembled on the tank (Figure 1), a magnetic field is transmitted through the non-magnetic tank wall between the magnetic driven and impeller assembly. Since there are the same number of poles in each the driver and impeller assemblies, the magnetic coupling is a synchronous design. The magnetic impeller will only operate slower than the magnetic driver if the maximum allowable design torque has been exceeded (i.e., decoupling torque).

As with magnetically coupled pumps, eddy current losses are not a concern with magnetically coupled mixers. Since the magnetic driver and impeller rotate relative to the stationary tank wall, eddy currents are generated in the tank wall. These eddy currents, which vary in magnitude based on the resistivity of the tank material, are converted into heat. Since mixer speeds are roughly 1/10 the speed of typical magdrive pumps, eddy current problems are not a concern with mixers. As

BOTTOM ENTRY MAGNETIC MIXER ASSEMBLY

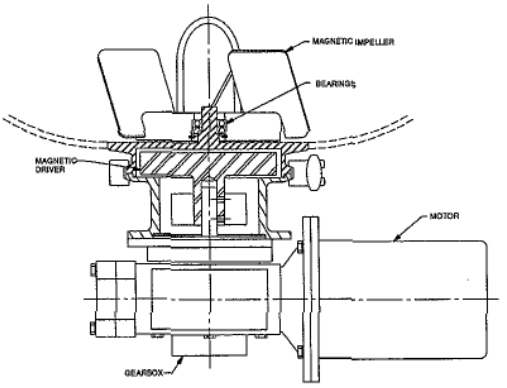


Figure 1

FACE TO FACE COUPLING

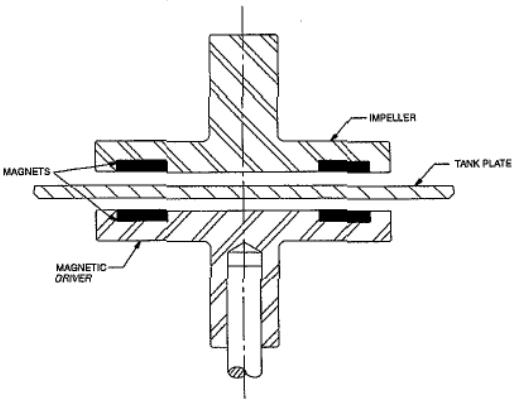


Figure 2

CO–AXIAL COUPLING

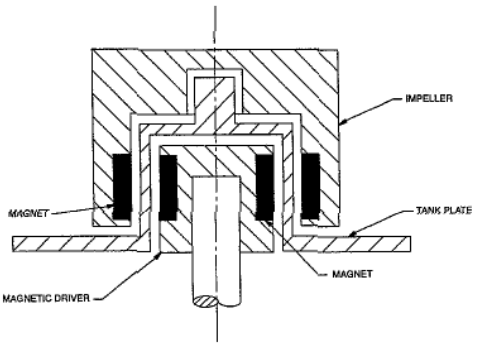


Figure 3

shown in Figure 4, eddy current losses increase exponentially with speed.

Bottom entering magnetically driven mixers primarily incorporate two different types of magnetic coupling designs, which consist of the "face to face" (Figure 2) and co-axial (Figure 3). Both are synchronous coupling designs which incorporate rare earth magnets consisting of either neodymium-iron-boron or samarium cobalt, depending on the process temperature conditions (i.e., ≤300°F neodymium, and ≥300°F, samarium cobalt).

Both coupling designs use the same principles for transferring torque. The co-axial design is primarily used for high torque (i.e., >1.5 hp @ 350 rpm) applications. This is because magnetic forces are perpendicular to the impeller axis, which in turn off-load the impeller bearings in the assembled position. The disadvantage of this design is that it is generally more expensive to manufacture and has more internal surfaces to clean than the face-to-face coupling design.

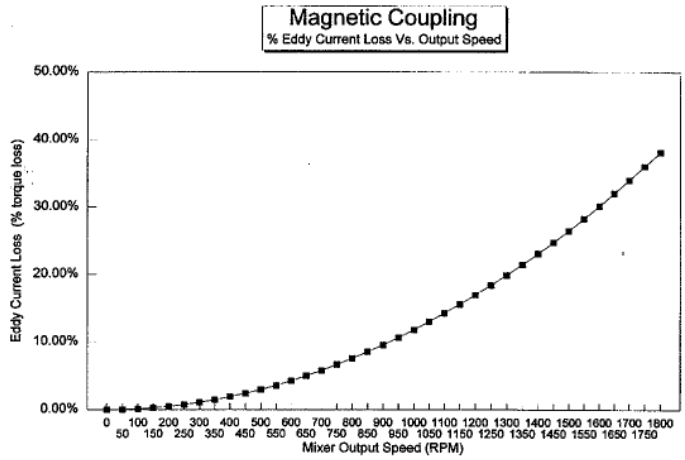


Figure 4

Bearing Configurations

Ceramic Sleeve Bearing

Until recently, there has primarily been only one bearing design used on bottom entry magnetically driven mixers. This being the sleeve or journal style bearing (Figure 5) manufactured from various materials (i.e., ceramic, plastic), depending on the material suitability and load requirements. Though this bearing design has been proven effective in many mixing applications, it has many inherent design concerns such as the following:

1. Particle generation.
2. Close clearance between rotor/stator restricts flow.
3. Brittleness.
4. Can not operate dry.

Particle generation is a problem that can be controlled but not prevented. The two-piece ceramic bearings consisting of various material combinations (zirconia, alumina, silicon carbide) are designed to support the impeller loads in both the axial and radial direction. These loads are supported by a bearing surface which is designed based on the PV (psi ft/min) allowable of the material. These bearing surfaces, which must be lubricated by the process fluid, are subject to wear over time. Because of the precision grinding and close running clearances (.001" to .003") these bearings must

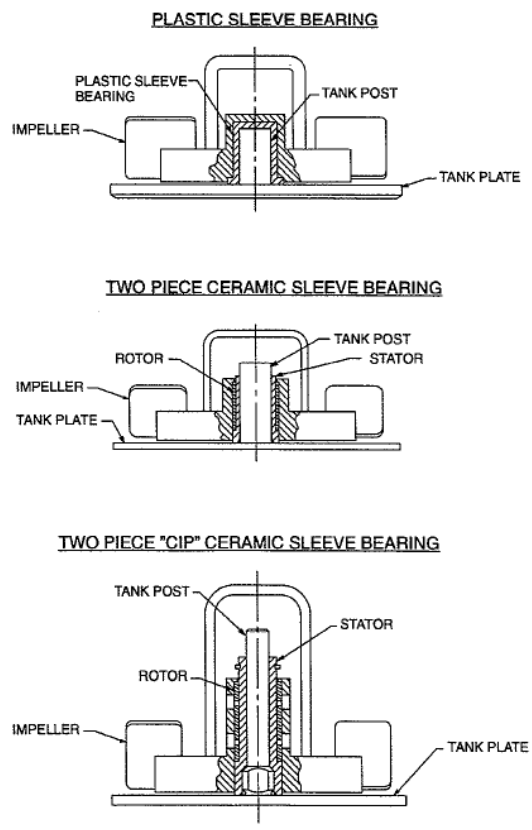


Figure 5

operate at, liquid flow-thru the bearing is restricted. For purposes of CIP cleanability, it is important to optimize the maximum flow rate through areas which are considered difficult to clean.

Hybrid Ceramic Ball Bearing

A new style bearing has recently been developed that addresses many of the design concerns regarding the ceramic sleeve bearing. This bearing design, referred to as hybrid ceramic ball bearing (Figure 6) because of its material combinations, offers the following design advantages:

1. Low particle generations.
2. Open flow-through design.
3. Impact resistant.
4. Can operate dry.

Since these bearings have rolling elements, the opportunity for particle generation is greatly reduced. The material combination consisting of silicon nitride balls, nickel alloy raceways, and a Teflon cage offer both high durability and excellent chemical resistance. Life testing under full load conditions accumulating over 10 million cycles (1,000 hrs.) produced no appreciable wear to the bearings. Not like ceramic sleeve bearings, which are prone to fracture if mishandled or magnetic decoupling occurs, these bearings are impact resistant. The dry running capability of this bearing lends itself to process and cleaning operations where liquid levels are commonly lowered. The open design of the hybrid ceramic bearing uniquely allows liquid to flow through the center of the bearing assembly (Figure 7). This feature enhances the cleanability of the bearing assembly during a CIP cycle.

CIP Design Considerations

With the ever increasing demand for high product purity in both the biotech and pharmaceutical industries, greater demands are being placed on mixer manufacturers to come up with improved CIP designs. As pointed out earlier, it is the mixer manufacturers responsibility to both design and evaluate the cleanability of any new design which is intended to be operated in a CIP process.

The following design considerations are recommended when developing a bottom entry magnetic mixer intended for CIP operation:

HYBRID CERAMIC BEARING DESIGN

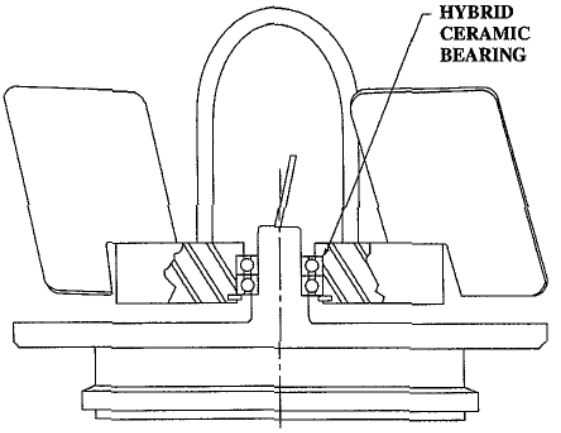


Figure 6

IMPELLER FLOW CHARACTERISTICS

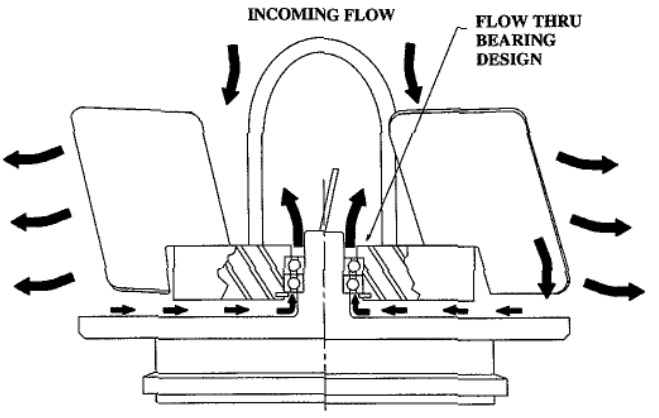


Figure 7

1. Maximize the running clearances between the impeller and tank plate assembly (Figure 8). Even though increasing the running clearance means a decrease in the torque output of the magnetic coupling design, it is critical for the cleanability of these surfaces. Generally, it has been shown through testing that running clearances less than 1/16" are difficult to clean.
2. Minimize the surface area in the bearing assembly. Generally, with any magnetic impeller, the bearing assembly is the most difficult place to CIP. This is due to the tight assembly clearances required with any style bearing. Optimize the bearing design to achieve the smallest exposed surface area.
3. When possible, design the bearing assembly with flow-through capabilities. An input and output flow pattern will help flush away residues remaining on the exposed surfaces. Inlet openings alone may have a tendency to dead-end CIP detergents, possibly trapping residues in the assembly.
4. If bearing assemblies need to be retained with a snap ring, it is best to keep the snap ring groove oversized to promote looseness in the assembly. This allows the snap ring to float in the groove allowing for CIP detergents to flow freely in the assembly.
5. When possible, design the impeller such that it pumps fluid through the bearing assembly (Figure 7). The higher the flow rate in and out of the bearing assembly will only enhance the cleanability of the design.

Other design considerations such as surface finish requirements were not mentioned since they are relevant to all the design recommendations above. Generally, a 15-20RA electropolish finish has been proven to be a very effective surface finish for CIP processes (Reference 2).

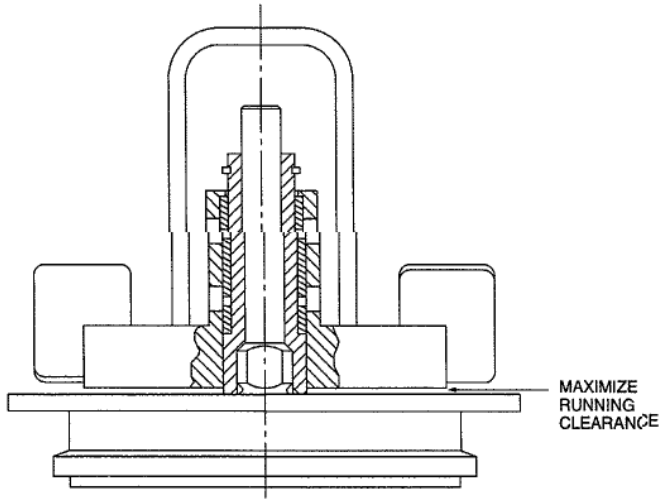
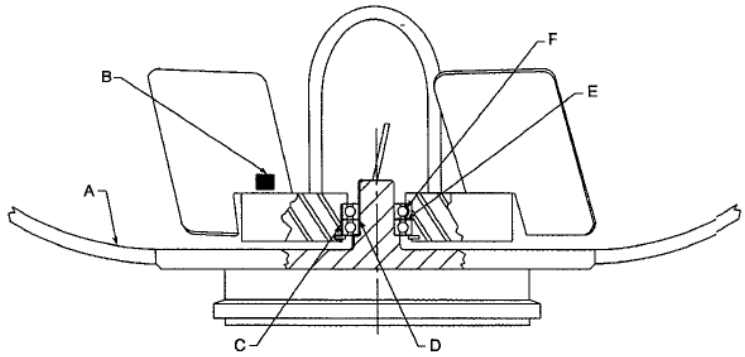


Figure 8

CIP Design Evaluation

Objective

As with any new design intended to be used in a clean-in-place (CIP) process, it is critical that the correct design considerations be used in the development phase and then evaluated using a CIP protocol. The objective of this evaluation is to qualitatively compare the CIP cleanability of a new impeller design using hybrid ceramic bearings (Impeller A) to an existing design which utilizes ceramic sleeve style bearings (Impeller B). Impeller B is a design that has been proven effective in many CIP applications over the past 10 years, and was considered to be a good baseline to compare to impeller A.

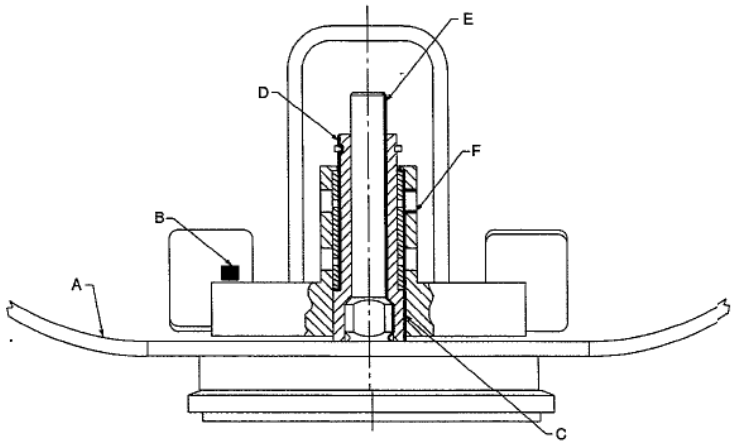


IMPELLER A

SWAB LOCATIONS

A	TANK WALL
B	IMPELLER BLADE
C	IMPELLER BORE AND SNAP RING GROOVE
D	TANK PLATE POST O.D.
E	BETWEEN BEARINGS
F	BEARING OUTER RACEWAY I.D.

Figure 9



IMPELLER B

SWAB LOCATIONS

A	TANK WALL
B	IMPELLER BLADE
C	IMPELLER I.D.
D	BEARING STATOR O.D. & SNAP RING GROOVE
E	TANK PLATE POST O.D.
F	IMPELLER FLOW THRU OPENINGS

Figure 10

Experimental Overview

An independent test lab (Silliker Laboratories) was commissioned to conduct CIP testing on the two impellers (Impellers A and B) as mentioned above. A cleaning protocol was developed by Silliker, and three different soils were chosen to contaminate the mixer assemblies. The three soils [1% bovine serum albumin (BSA; protein matrix), corn oil (fat matrix), and 50% honey (carbohydrate matrix)] were all chosen because of their compositional differences and difficulty to clean. Each soil was spiked with a cocktail of bacteria at a level of 100,000-1,000,000 cells, or colony forming units (CFU) per mL.

This served to examine the removal and/or elimination of microorganisms via a CIP process. After the CIP process, various swab and rinse samples were collected and analyzed for residual soil and bacteria. This study was only intended to compare the CIP cleanability of both impeller assemblies and was not intended to validate a cleaning protocol.

Materials and Methods

Test Organisms

The test organisms were selected from the Silliker Research Culture Collection (SRCC). The microorganisms [*Escherichia coli* (SRCC 1110), *Staphylococcus epidermidis* (SRCC475), and *Pseudomonas aeruginosa* (SRCC 60)] were each propagated in 100 mL of Tryptic Soy Broth (TSB) at 35°C for 24 hours. Each culture was pelleted by centrifugation at 16,000 x g for 10 minutes at 4°C. Each pellet was combined in a final volume of 100 mL of sterile phosphate buffer. The number of organisms in the cocktail was determined by pour plate methodology using Tryptone Glucose Yeast Extract Agar (TGY) incubated at 35°C for 24 hours. The cocktail was stored at 4°C while determining counts and this cocktail was used for product inoculation.

Test Equipment

1. 50L test tank (316 S.S.) with a 10-20 RA surface finish on the inside wetted surfaces (Figure 11).
2. (1) Lightnin model MBH410P18 MagMixer with Impeller B (316 S.S.) having a 10-20 RA electropolish finish. Output speed = 175 RPM.
3. (1) Lightnin model MBI410 MagMixer with Impeller A (316 S.S.) having a 10-20 RA electropolish finish. Output speed - 175 RPM.

Experimental Process

The CIP study was conducted in two parts. Part I was designed to examine and swab specific "hot spots" (surface locations with potential residue) (Figure 9 & 10), following a CIP cleaning protocol. These "hot spots" were predetermined using a riboflavin test procedure. Part II was designed to examine the CIP cleanability of the impeller as a whole. Both impellers were installed and operated simultaneously during the contamination and CIP cleaning cycles.

Part I

Two soils, 1% BSA and corn oil, were selected for this portion of the study. Each soil was examined in duplicate. The procedure is detailed below:

1. Six gallons of soil was added to the mixing tank.
2. The soil was inoculated with the cocktail of microorganism to achieve a final inoculum level of approximately 100,000 to 1,000,000 CFU/mL.
3. The inoculated soil was mixed in the test tank for 10 minutes at 175 RPM, both mixers running at the same time.
4. After mixing for 10 minutes, the soil was drained and a swab sample of the tank wall was collected. An 84.5-CM^2 area was sampled using a 3.5 x 3.5-inch cotton swab. Two samples were collected, one for APC and another for either protein or fat.

TEST EQUIPMENT SETUP

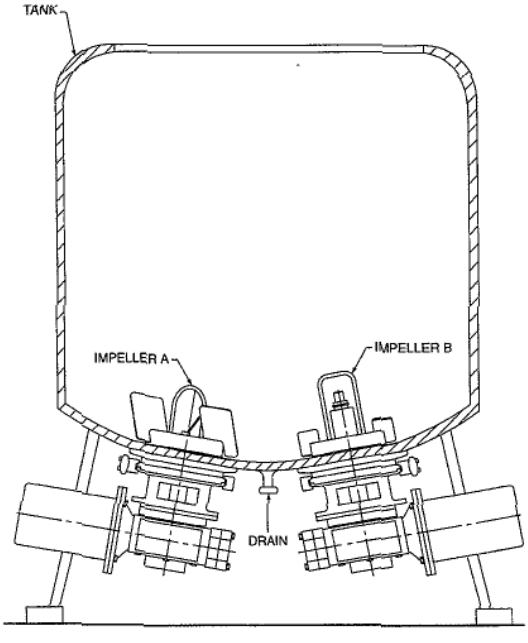


Figure 11

5. After collecting samples, the tank and impellers were rinsed with warm (110°F) water to loosen and wash away the bulk of the soil.
6. The tank was then filled with 145°F water and the CIP detergent added. The final detergent solution was 1%. The detergent used was Alcojet made by Alconox, Inc., New York, NY 10003. The detergent was an alkaline base having a final ph of approximately 12.0.
7. The impellers were operated in place with the detergent for 20 minutes at 175 rpm.
8. After the CIP cycle, the tank was drained.
9. The tank was then filled with six gallons of hot water (210°F) and circulated for five minutes.
10. The tank was then drained and rinsed with deionized water for approximately one minute.
11. After the final rinse, designated "hot spots" on each impeller and the tank wall was swabbed as described above. Each site on the impellers had a specific surface area sampled (Figure 9 & 10) and the tank wall was sampled as described above.
12. Final swabs of the total surface of each impeller were also sampled.

Part II

Three soils, 1% BSA, corn oil, and 50% honey, were selected for this portion of the study. Each soil was examined in duplicate. The procedure is detailed below:

1. Steps 1 through 10 were performed as described in Part I.
2. Following Step 10, each impeller was removed and scrubbed with a cotton swab in 500 mL of deionized water.
3. The rinse water was then analyzed for APC, TOC, protein, or fat.

Analysis of Samples

Samples collected were tested using methods described below. Swab samples collected for APC were stomached for 1 minute in 100 mL of sterile phosphate buffer. The homogenate was filtered through a sterile membrane filter unit (Millipore) and overlaid with TGY (35°C, 24 hours). Colonies were counted, divided by the surface area sampled, and reported as CFU/cm^2. Samples were analyzed by TOC, fat or protein and were reported in units per cm^2.

- Aerobic Plate Count (APC) bacteria, membrane filter method: Method outlined in Silliker Microbiology Methods Manual.
- Total Organic Carbon (TOC): Method outlined in Environmental Protection Agency (EPA) method number 415.1. Sensitivity, 1 rpm.
- Fat: Soxhlet method. Sensitivity, 0.1 mg of fat.
- Protein: Nitrogen combustion method (ref. method). Sensitivity, 0.2 mg of protein.

Discussion and Results

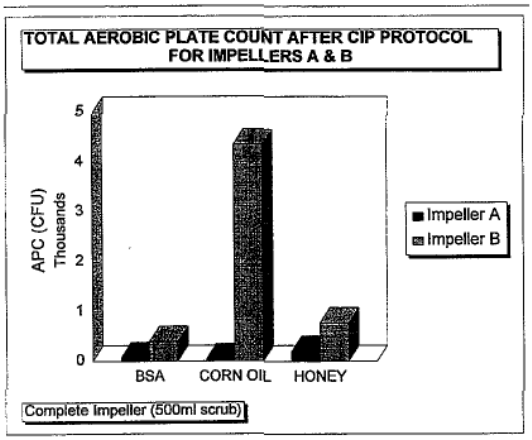
In Part I, the objective was to examine potential "hot spots" (as per Figures 9 & 10) for any residue that could have remained following a CIP cycle for both impellers.

In Part II, the objective was to compare the cleanability of each impeller as a whole unit, following a CIP cycle for both impellers.

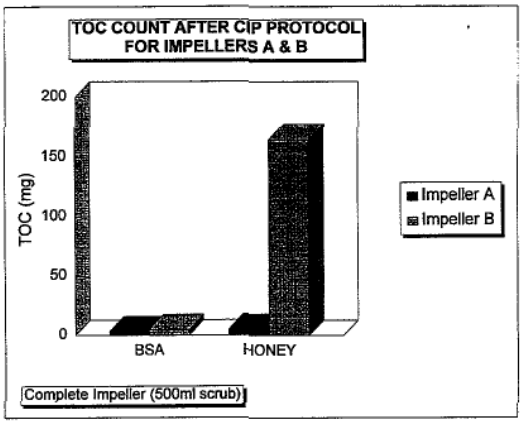
Tables 1, 2, 6, and 7 show the cleanability of both impeller designs regarding the designated "hot spots" (Figure 9 & 10) after contaminations with 1% BSA or 100% corn oil. The data in each table showed a reduction in APC bacteria and soil following each protocol run. The data in the tables also indicates where the difficult areas are to clean. As with any cleaning protocol, one of the most important resultants is the total residual remaining for the entire impeller assembly. Tables 3-5 show total APC and protein counts for BSA and Tables 8 and 9 show total APC and fat counts for 100% corn oil. Tables 10, 11 show total APC and TOC counts for 50% honey.

Tables 12 and 13, and graphs 4-5 show the total percent APC and percent soil remaining on each impeller when compared to the initial contamination levels. This data (Graph 1) shows that in all three soils tested, the percent APC levels were lower for Impeller A. One interesting note is that the percent soil levels using the BSA were slightly higher for Impeller A but lower for both corn oil and honey when compared to Impeller B. This data would indicate that "sticky", more difficult soils would be easier to clean in Impeller A than Impeller B. Also, water like soils, as with the BSA solution, would have similar levels of cleanability between the two impeller designs. It would be expected, based on the data, to see higher APC counts for Impeller A than B, simply due to the higher percent of soil residue remaining. This was not the case (Graphs 4 & 5), and could possibly be due to higher temperature levels being reached in the bearing of Impeller A over Impeller B. The increase in temperature in Impeller A could have been attributed to the flow-thru designs feature in the hybrid ceramic bearings. The data in Tables 1, 2, 6, and 8, regarding the swab recovery levels for the site locations specified, possibly vary for the following reasons.

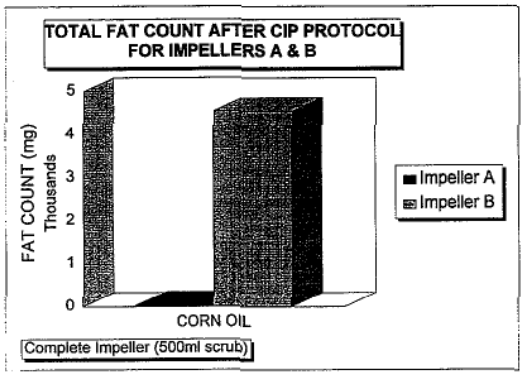
During the removal of Impeller B, for purposes of swabbing, it was witnessed that small amounts of corn oil residue leaked out of the bearing assembly and into the test tank. This residue was non-recoverable and could have contributed to the lower APC counts between Impellers (A & B) for the "hot spots" in the bearing assembly. This did not seem to happen during the removal of Impeller A during the same test. (This residue was able to be recovered for each of the 500 mL scrubs per Tables 3, 8, 9, 10, and 11.)



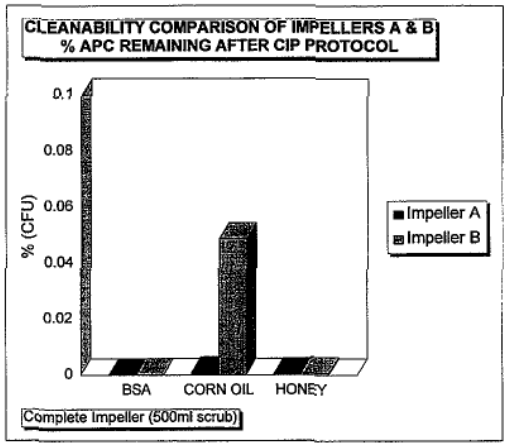
Graph 1



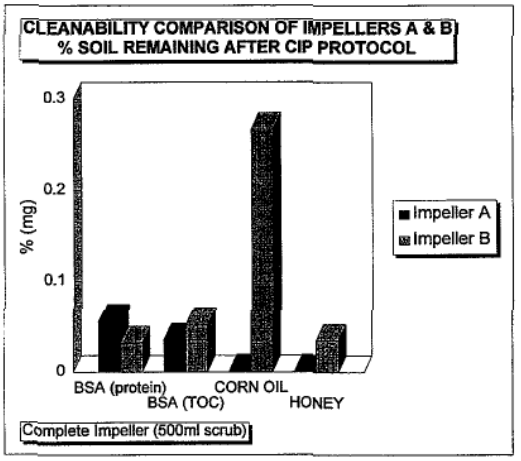
Graph 2



Graph 3



Graph 4



Graph 5

Conclusions

Two objectives were addressed in this study. The first objective was to identify and evaluate potential "hot spots" for cleanability in each impeller design. The second objective was to examine the cleanability of each impeller design as a complete unit. The study *demonstrated that each impeller design was cleanable.* Certainly, with more rigorous cleaning protocol (i.e., time, temperature, detergents), these impeller designs may show even greater cleanability or perhaps reductions of contaminants below detectable limits. The study also demonstrated that the cleanability of Impeller A may have greater success when sticky, hard to clean soils are present. The study showed that Impeller A was generally more cleanable than Impeller B for each of the three soils evaluated.

As with any new product developed to operate in CIP process, it is important to compare its cleanability *with a similar product that has been proven effective in* similar applications. Since Impeller B has been used successfully in various CIP processes for the past 10

years, it was considered an effective baseline in this evaluation. The test evaluation conducted, successfully compared the qualitative results between Impeller A and B for the given test equipment and protocol run. The data enclosed in this report is not intended and should not be used as a baseline to other equipment or protocols.

References

1. Silliker Laboratories Group, Inc.
   Research Center
   160 Armory Drive
   South Holland, IL 60473
2. Franca, Jorge Villa, Zambrano, Eva Monroy. (Nov/Dec 1985). "Optimization of Cleanability." Pharmaceutical Engineering.

Table 1

Impeller A - Cleanability of 1% Bovine Serum Albumin

		APC (CFU)		Protein (mg)	
Swab Location	Sites	Before CIP	After CIP	Before CIP	After CIP
A	Tank Wall	475000	32	8.8272	0.3555
B	Impeller Blade	-	18	-	0.2020
C	Impeller Bore And Snap Ring Groove	-	11	-	0.1248
D	Tank Plate Post O.D.	-	5	-	0.0543
E	Between Bearings	-	3	-	0.0320
F	Bearing Outer Raceway I.D.	-	3	-	0.0292

Table 2

Impeller B - Cleanability of 1% Bovine Serum Albumin

		APC (CFU)		Protein (mg)	
Swab Location	Sites	Before CIP	After CIP	Before CIP	After CIP
A	Tank Wall	475000	32	8.8272	0.3555
B	Impeller Blade	-	4	-	0.0017
C	Impeller Bore	-	11	-	0.0014
D	Bearing Stator O.D. & Snap Ring Groove	-	4	-	0.0035
E	Tank Plate Post O.D.	-	6	-	0.0018
F	Impeller Flow Thru Openings	-	3	-	0.0020

Table 3

A & B Comparison - Cleanability of 1% Bovine Serum Albumin

		APC (CFU)			
		Impeller A	Impeller B	Impeller A	Impeller B
Swab Location	Sites	Before CIP	Before CIP	After CIP	After CIP
A	Tank Wall	475000	475000	32	32
	Complete Impeller (500ML scrub)	-	-	75	395

Table 4

A & B Comparison - Cleanability of 1% Bovine Serum Albumin

		Protein (mg)			
		Impeller A	Impeller B	Impeller A	Impeller B
Swab Location	Sites	Before CIP	Before CIP	After CIP	After CIP
A	Tank Wall	8.8272	8.8272	0.3555	0.3555
	Complete Impeller (500ML scrub)	-	-	1.810	1.8388

Table 5

A & B Comparison - Cleanability of 1% Bovine Serum Albumin

		TOC (mg)			
		Impeller A	Impeller B	Impeller A	Impeller B
Swab Location	Sites	Before CIP	Before CIP	After CIP	After CIP
A	Tank Wall	25.4000	25.4000	0.6550	0.6550
	Complete Impeller (500ML scrub)	-	-	3.3250	4.8500

Table 6

Impeller A - Cleanability of 100% Corn Oil

		APC (CFU)		Fat (mg)	
Swab Location	Sites	Before CIP	After CIP	Before CIP	After CIP
A	Tank Wall	13850	100	4631.150	138.925
B	Impeller Blade	-	14	-	1.450
C	Impeller Bore And Snap Ring Groove	-	20	-	4.400
D	Tank Plate Post O.D.	-	9	-	83.850
E	Between Bearings	-	32	-	643.800
F	Bearing Outer Raceway I.D.	-	10	-	3.900

Table 7

Impeller B - Cleanability of 100% Corn Oil

		APC (CFU)		Fat (mg)	
Swab Location	Sites	Before CIP	After CIP	Before CIP	After CIP
A	Tank Wall	13850	100	4631.150	138.925
B	Impeller Blade	-	4	-	4.950
C	Impeller Bore	-	7	-	333.050
D	Bearing Stator O.D. & Snap Ring Groove	-	1	-	13.050
E	Tank Plate Post O.D.	-	3	-	15.200
F	Impeller Flow Thru Openings	-	24	-	2.150

Table 8

Impeller A & B Comparison - Cleanability of 100% Corn Oil

		APC (CFU)			
		Impeller A	Impeller B	Impeller A	Impeller B
Swab Location	Sites	Before CIP	Before CIP	After CIP	After CIP
A	Tank Wall	13850	13850	100	100
	Complete Impeller (500ML scrub)	-	-	38	4353

Table 9

Impeller A & B Comparison - Cleanability of 100% Corn Oil

		Fat (mg)			
		Impeller A	Impeller B	Impeller A	Impeller B
Swab Location	Sites	Before CIP	Before CIP	After CIP	After CIP
A	Tank Wall	4631	4631	139	139
	Complete Impeller (500ML scrub)	-	-	26.00	4545.00

Table 10

Impeller A & B Comparison - Cleanability of 50% Honey Solution

		APC (CFU)			
		Impeller A	Impeller B	Impeller A	Impeller B
Swab Location	Sites	Before CIP	Before CIP	After CIP	After CIP
A	Tank Wall	170000	170000	79	79
	Complete Impeller (500ML scrub)	-	-	200	773

Table 11

Impeller A & B Comparison - Cleanability of 50% Honey Solution

		TOC (mg)			
		Impeller A	Impeller B	Impeller A	Impeller B
Swab Location	Sites	Before CIP	Before CIP	After CIP	After CIP
A	Tank Wall	1282.5000	1282.5000	0.7250	0.7250
	Complete Impeller (500ML scrub)	-	-	5.2750	164.2750

Table 12

Cleanabilty Comparison of Impellers A & B

% APC Remaining After CIP Protocol (CFU)

Swab Location	Soil	Impeller A	Impeller B
Complete Impeller	1% Bovine Serum Albumin (BSA)	0.004%	0.013%
Complete Impeller	100% Corn Oil	0.073%	4.865%
Complete Impeller	50% Honey	0.032%	0.070%

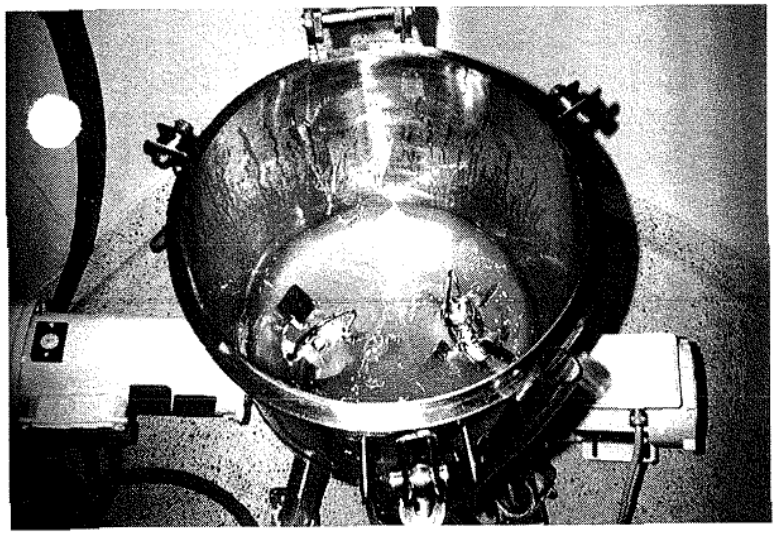
Table 13

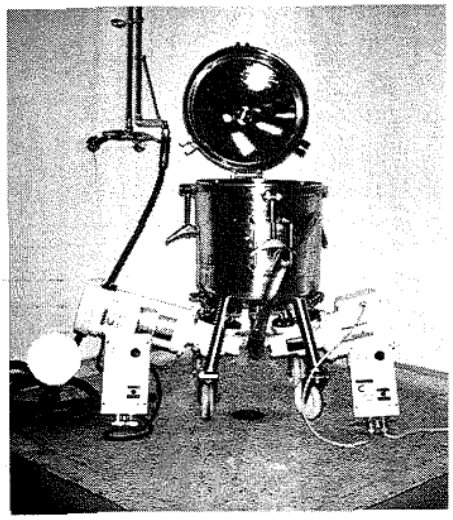
Cleanabilty Comparison of Impellers A & B

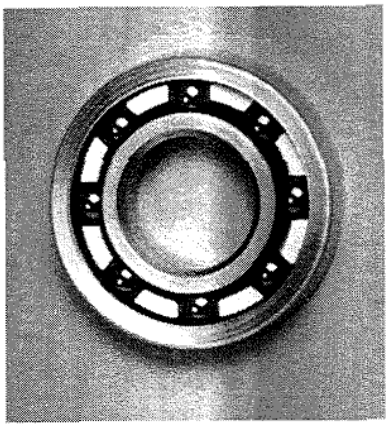
% Soil Remaining After CIP Protocol

Swab Location	Soil	Test	Impeller A	Impeller B
Complete Impeller	1% Bovine Serum Albumin (BSA)	Protein	5.567%	3.225%
Complete Impeller	1% Bovine Serum Albumin (BSA)	TOC	3.553%	5.183%
Complete Impeller	100% Corn Oil	Fat	0.152%	26.639%
Complete Impeller	50% Honey	TOC	0.112%	3.477%

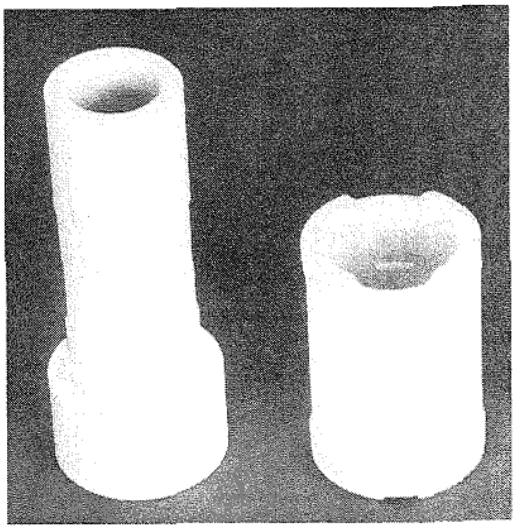
Photos of Test Setup and Equipment



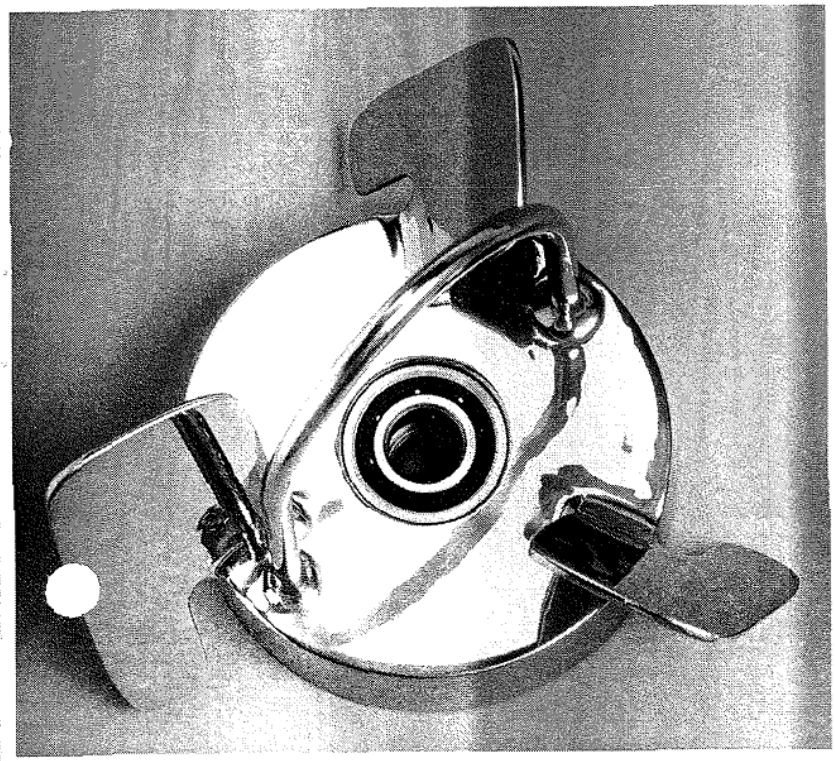




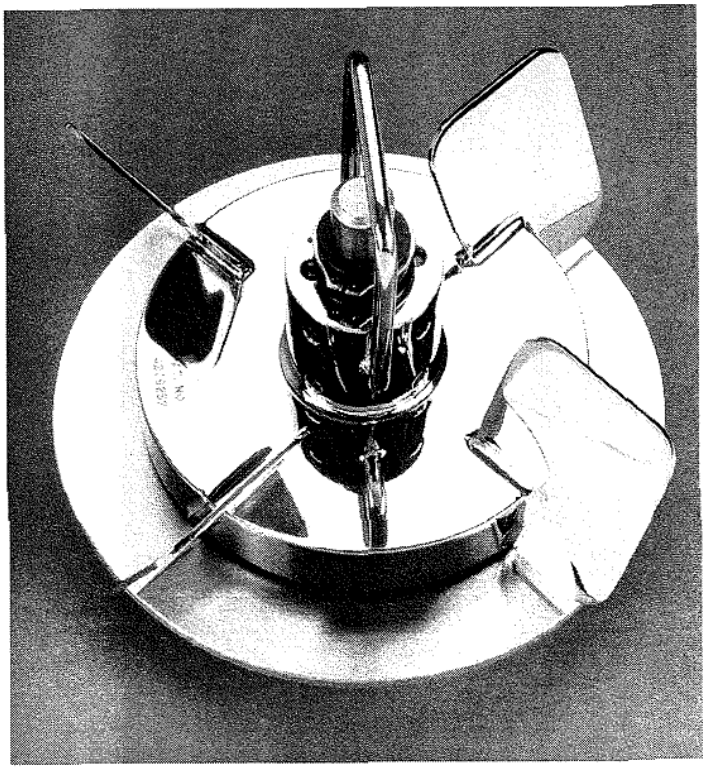
Impeller A Bearing Design



Impeller B Bearing Design



Impeller A



Impeller B

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