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PharMix® SC System Comparison Testing Tech Data Sheet

X-7367-0

Single Use Mixing: How Does It Compare to Conventional Mixing?

Introduction

The need for flexibility has accelerated the adoption of single-use processing solutions in many industries. One of the most common but difficult tasks is sanitary mixing applications. The common issue with implementing single-use mixing technology is achieving desirable, fast, efficient mixing results that can be scalable. Most single-use mixing systems in the marketplace today, have shown they achieve desirable mixing results, but have they compared themselves directly to a conventional type mixing system? Have they done comparisons to show how they perform against a general purpose mixing application, that have had years of success? DCI, Inc. has been manufacturing mixers, such as the PharMix Agitator line, for sanitary industries for over 55 years. Using that experience and knowledge in conventional mixing when developing the PharMix SC System made perfect sense. End users also have had a baseline in conventional mixing systems for their particular applications for years. Comparing the two, should allow a much easier understanding and implementation of a single-use mixing system, such as the PharMix SC System.

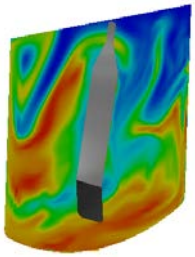
During the development stages, a targeted goal was to:

1. Have the design resemble a typical conventional mixing system.

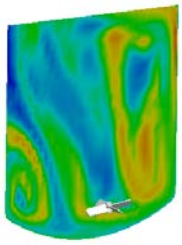
2. Achieve a specific turnover rate. A turnover rate of 2 turnovers per minute was chosen as the goal. This rate seems to be acceptable for most general mixing applications, especially those found in BioPharm applications.

3. Dissolve a 10% granular salt solution in 5-10 minutes. Some systems only claim to mix a 5% or 2.5% salt solution.

4. Maintain aseptic boundary with no agitator seals/bearings



The first design phase was using CFD (Computational Fluid Dynamics) to try to get the feel for the mixing capability of the PharMix SC System. This was compared to conventional axial turbine props that were also analyzed using CFD. The system was built and tested using beads of different specific gravities to optimize the mixing motion using the mixing paddle. The final tests were pH indicator and 10% salt solution testing. The following chart shows the systems that were compared.



* US Patent No.8,152,362

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Volume	System	Prop	Speed (RPM)	Turnover/min
200L	PharMix SC	Standard	52	TBD
200L	Conventional	5.75 inch diameter turbine	350	4.5 calculated
1000L	PharMix SC	Standard	45	TBD
1000L	Conventional	9.5 inch diameter turbine	350	4.5 calculated

Conductivity Testing:

One method to compare the SC System to a conventional system was to prepare a salt solution. Salt solution testing can prove the capability of dissolving granular solids into a liquid, especially since the granular salt settles to the bottom.

Experiment Procedure

In this experiment a PharMix SC System and a conventional axial turbine prop was used to mix a 10% (wgt/vol) NaCl solutions.

The protocol was to fill the vessel with the appropriate volume of DI Water, then add the appropriate amount of granular salt with the mixer not running. Upon completion of salt addition, immediately start the mixer and run continuously for 10 minutes. Two conductivity probes were installed 4” and 6” deep from the top of the Mixing BioContainer based on CFD analysis showing last mixed location.

Volume	**200 L**	**1000 L**
DI Water	190.8 L	953.8 L
Salt	20 kg	100 kg
Probe depth	4”	6”

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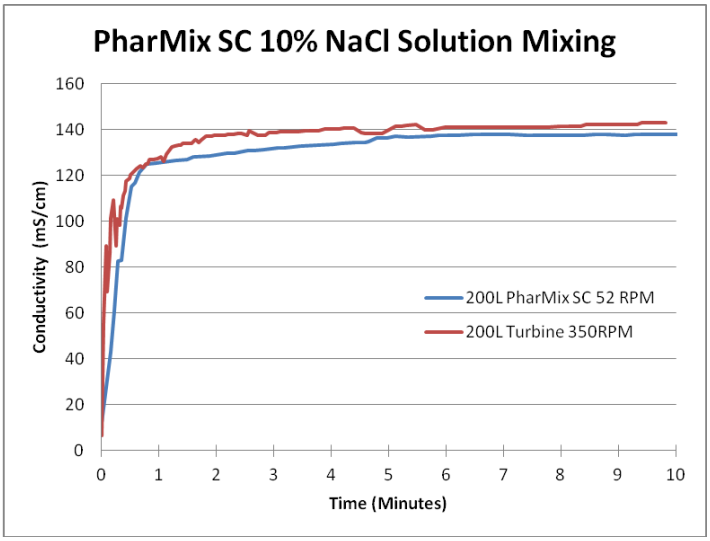
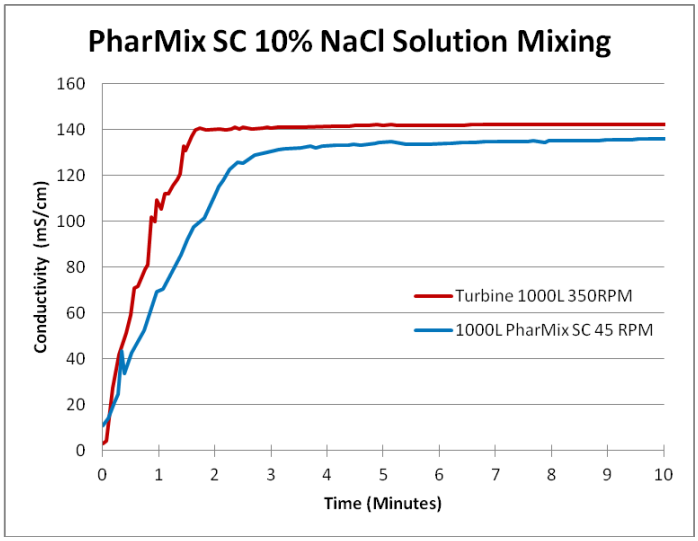
Results and Discussion

The results were recorded and tabulated and shown in the tables below.

Based on the results, it is clear that the solution was dissolved fully and achieved homogeneity in both volumes. Although the curves may not be truly identical, they follow the same trend and are completely mixed in less than 5 minutes, which will meet or exceed the requirements of most applications .





Based on the conductivity testing, one can see that the PharMix SC System is fully capable of consistently dissolving a 10% salt solution in less than 5 minutes in either a 200L or scaled up 1000L volume. It also shows that the conductivity testing of a PharMix SC System or a conventional turbine prop mixer were nearly identical.

Note: temperature correction was not used in charting the data, there was a 2-6 degree C temp fluctuation during testing.

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pH Indicator Testing:

One method to compare the SC System to a conventional system was to perform pH indication testing which features a liquid-liquid mixing of similar viscosities and specific gravity, under specific conditions and time frame.

Experiment Procedure

In this experiment a PharMix SC System and a conventional axial turbine prop was used to mix pH indicating solutions.

The protocol was to fill the vessel with the appropriate volume of DI Water, add then add an amount of 1% phenolphthalein solution. The mixer was turned on for 2 minutes. While the mixer was running a sodium hydroxide (NaOH) solution was added and timing started. The solution will turn from clear to pink (basic). Once mixed a phosphoric acid solution (H_3PO_4) was added to change the solution back to clear (acidic) and was timed.

Volume	**200 L**	**1000 L**
DI Water	200 L	1000 L
Phenolphthalein (approx 1% vol)	95 mL	475 mL
NaOH (approx 27% vol)	740 mL	3700 mL
H_3PO_4 (approx 40% vol)	740 mL	3700 mL
Agitator Speed	52 RPM	45 RPM

Results and Discussion

The results were based on visual observation and timing determined by the clock on the video. The changes can be clearly seen in photo stills of the videos. The actual videos of the entire process provide much more clarity. (visit: www.pharmix-sc.com) The 200L size was performed in a clear acrylic tank and a side view could be shown, the 1000L was performed in a standard stainless steel tank with a top view. The change from clear to pink were fairly rapid, the change from pink to clear was slightly slower and gave a better representation of how the fluid was mixing. The mixing patterns viewed were closely related to previous CFD analysis completed. See pages 6-7 for photo results.

Based on the results, both were fully mixed in 30 seconds or less. The exact timing is not as critical as identifying the mixing pattern and completeness of mixing. It can be determined that using the PharMix SC System may not give as fast mixing results to a conventional mixing turbine system but it still mixes effectively and in an efficient manner, with lower shear compared to a conventional turbine. Based on the results, this would meet or exceed any liquid-liquid mixing requirements of similar viscosity and specific gravity. These results would especially meet those applications using acid-base reactions where pH change in a certain time frame is critical. Our mixing study also proves how quickly pH may be adjusted in the total volume without dead spots or areas of concern. It also shows that the pH indicator testing of a PharMix SC System or a conventional turbine prop mixer were near identical in nature.

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Based on the standard conventional system and time, a method to conservatively (worst case) compare turnover rate using the pH indicator actual results was determined as:

Turnover factor (Tf)~ (4.5 TO/60 sec) = (Tf/16 sec) so Tf = 1.2
Turnover factor (Tf)~ (4.5 TO/60 sec) = (Tf/17 sec) so Tf = 1.275

Using an average Tf=1.24 one can calculate a theoretical turnover rate for the PharMix SC as follows:

Turnover (x) = (x TO/60 sec) = (1.24/actual sec)
200L at 25 sec, x = 3.0
1000L at 30 sec, x = 2.5

Volume	System	Prop	Speed (RPM)	Turnover/min
200L	PharMix SC	Standard	52	3.0 theoretical by comparison
200L	Conventional	5.75 inch diameter turbine	350	4.5 calculated
1000L	PharMix SC	Standard	45	2.5 theoretical by comparison
1000L	Conventional	9.5 inch diameter turbine	350	4.5 calculated

Final Summary:

The goals of developing the PharMix SC System, Single Campaign mixing system were achieved;

1. The design resembles a typical conventional mixing system with a round container and similar height to diameter ratios. There are no rectangular shapes or dead zone corners that are typically not found in conventional mixing systems. The bottom of the tank is dished, similar to that of conventional systems for mixing performance and drainage. The prop does not rotate, however, the patented mixing motion simulates rotation of the paddle near the bottom of the tank and pumped downward and therefore creates a similar flow pattern to conventional systems.
2. A turnover rate of 2 turnovers per minute was chosen as the goal, and by our testing methods, the goal met and exceeded in what was deemed to be a worst case scenario. This rate is acceptable for most general mixing applications. Remember, the time is not critical, the consistency and end result is. Gentle and effective low shear mixing was achieved.
3. The system can dissolve a 10% granular salt solution in 5 minutes. This is not a 5% or 2.5% like others which are much easier to achieve.
4. The aseptic boundary was maintained by eliminating any seal or bearings.

Based on the pH indicator testing and conductivity testing, one can see that the PharMix SC System is fully capable of achieving efficient and homogenous mixing. Comparing the SC System to a conventional prop mixer is proof of its mixing capability and scalability. One should consider this comparison due to the history of success of conventional systems used when choosing a single use system.

This technical data sheet can be used as a reference for many mixing applications, however all specific applications should be evaluated. Contact our specialists for assistance with any PharMix SC System process solution.

Reference: See TDS X-7365 for pH Indicator Testing and X-7366 for Conductivity Testing of the PharMix SC System. Also see TDS X-7369 for CFD Comparison of the PharMix SC System

* US Patent No.8,152,362

Photo results:

Note: The videos of the entire process provide much more detail and clarity visit: www.pharmix-sc.com

200L SC System 52 RPM

0 Sec. 10 Sec. 15 Sec. 20 Sec. 25 Sec. (Fully Mixed)

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200L Turbine 350 RPM

0 Sec. 10 Sec. 15 Sec. 16 Sec. (Fully Mixed)

* US Patent No.8,152,362

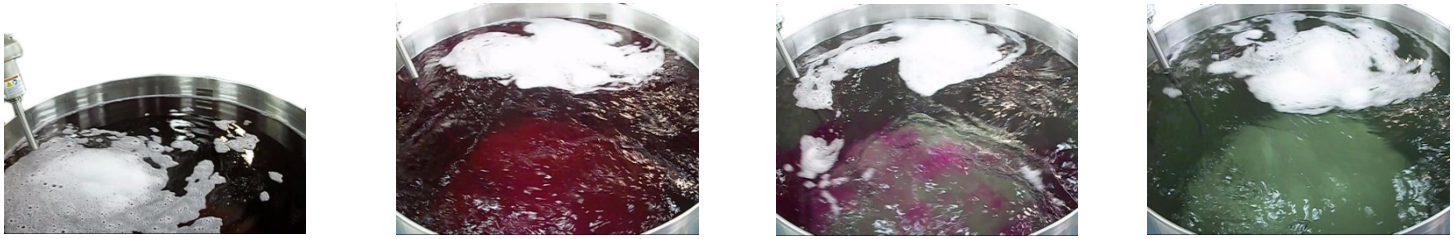
Photo results:

Note: The videos of the entire process provide much more detail and clarity visit: www.pharmix-sc.com

1000L SC System 45 RPM

0 Sec. 10 Sec. 15 Sec. 20 Sec. 25 Sec. 30 Sec (Fully Mixed)

1000L Turbine 350 RPM



0 Sec. 10 Sec. 15 Sec. 17 Sec. (Fully Mixed)

The PharMix SC System* is a Single Campaign (single-use) mixing system. It is suitable for a wide range of industries utilizing a round, single-use 3D Mixing BioContainer with a self-contained mixing paddle with no seals, bearings or breach of the aseptic boundary. It features a patented* unique, multi-plane mixing motion. This technical data sheet can be used as a reference for many mixing applications, however all specific applications should be evaluated. Contact our specialists for assistance with any PharMix SC System process solution.

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