

Mobius® MIX500 Disposable Mixing System Characterization

Introduction

The need for faster cycle times and higher levels of operational flexibility has accelerated the adoption of single-use processing solutions in the biopharmaceutical industry. In response, we introduced the Mobius® MIX systems – a family of disposable mixing systems that include the MIX100 (100 L maximum operating volume), the MIX200 (200 L maximum operating volume), and the MIX500 (500 L maximum operating volume). The Mobius® disposable MIX systems include a carrier, a disposable Mobius® process container with an integral magnetically driven levitating impeller, a motor, and an electronic drive unit.

One of the most common daily process tasks in the biopharmaceutical industry is the mixing of media and buffer solutions for use in both upstream and downstream unit operations. The Mobius® MIX systems have been successfully utilized for mixing a variety of media and buffer solutions. The following study provides characterization data for the performance of the Mobius® MIX500 system at different impeller speeds, operating volumes, and viscosities, as well as operations in a cold room environment. In addition, the information presented in this Technical Brief can be used as a reference for numerous mixing applications.



Test Summary

1. Mixing Time for 1X PBS buffer components at 250 rpm and 125 rpm in 500 L total operating volume
2. Mixing Time for 1X PBS buffer components at 250 rpm in 500 L, 250 L, 125 L, and 110 L total operating volume
3. Operation under ambient conditions at two different viscosities
4. Operation in a cold room environment

Parameter	Value/range
Maximum Mixing Volume	500 L at 250 rpm
Bag Operating Pressure	Atmospheric
Mixing Operating Viscosity	0 to 40 cP
Impeller Speed	0 to 250 rpm
Environmental Operating Temperature	4 to 30 °C
Storage Temperature	0 to 40 °C
Power Supply Voltage	208 VAC 3 phase or 230 VAC single phase
Operating Humidity Range (RH)	15% to 95% (non-condensing)
Storage Humidity Range (RH)	15% to 95% (non-condensing)

General Experimental Protocol

1. Add the appropriate volume of water to the Mobius® MIX500 system
2. Set the impeller to the specified speed
3. Add the specific material to the Mobius® MIX500 system through the top bung port as a single addition
4. Monitor the top of the system for conductivity at appropriate time intervals. (Reference Mobius® MIX100 Characterization Technical Note, Lit. No. TB1701EN00 for information regarding sampling location.)
5. Continue mixing until there is visual confirmation that all solids have been incorporated and that 10 consecutive measurements are stable or the measurements have been stable for a minimum of 10 minutes

Results

1. Mixing Time for 1X PBS buffer components at 250 rpm and 125 rpm in 500 L total operating volume
 - t_m at 250 rpm = 10 minutes
 - t_m at 125 rpm = 15 minutes

A general recommendation for solid-liquid mixing applications in the Mobius® MIX500 system is to operate at a minimum impeller speed of 125 rpm. The system is also capable of maintaining lower impeller speeds for applications such as liquid-liquid mixing. It is important to note that all specific applications will need to be evaluated prior to implementation.

2. Mixing Time for 1X PBS buffer components at 250 rpm in 500 L, 250 L, 125 L, and 110 L total operating volume
 - t_m at 500 liters = 10 minutes
 - t_m at 250 liters = 8 minutes
 - t_m at 125 liters = 5 minutes
 - t_m at 110 liters = 4 minutes

While system volumes less than 110 liters were tested, the impeller was not fully covered with liquid. The minimum operating volume should be considered 110 liters at 250 rpm for the Mobius® MIX500 system.

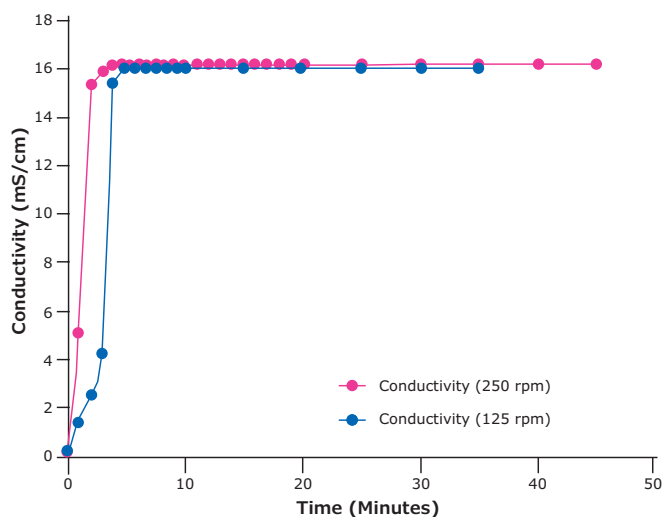


Figure 1. Conductivity vs. Mixing Time at 250 rpm and 125 rpm

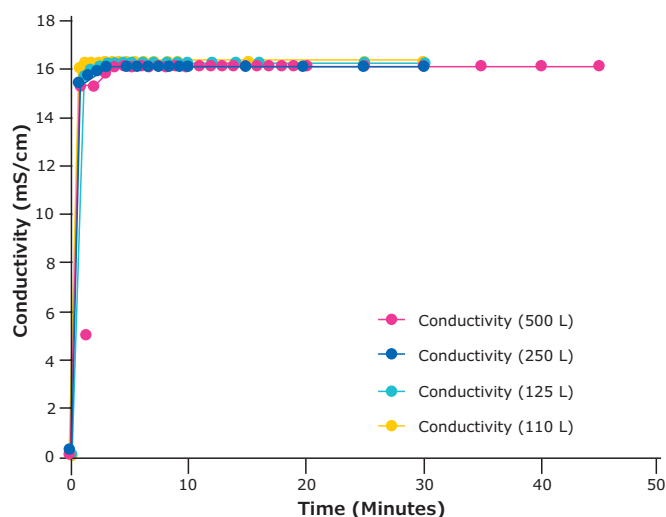


Figure 2. Conductivity vs. Mixing Time at 500 L, 250 L, 125 L, and 110 L at 250 rpm

3. Operation under ambient conditions at two different viscosities

Viscosity:

- t_m at 32 cP (24 °C) = 60 minutes
- t_m at 82 cP (24 °C) = 75 minutes

The mixing time is reported for 1X PBS buffer components in a solution of the specified viscosity.

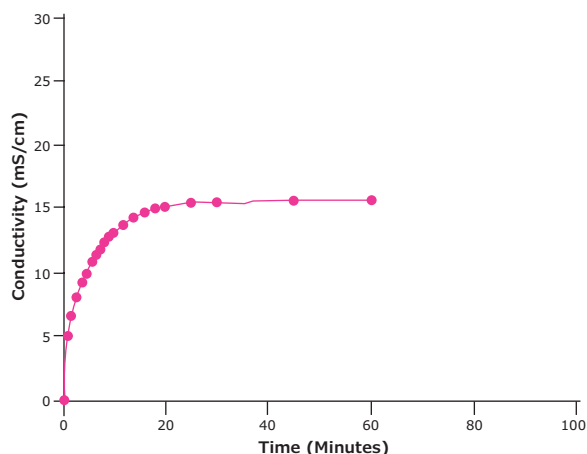


Figure 3. Conductivity vs. Mixing Time at 32 cP and 24°C at 250 rpm

4. Operation in a cold room environment

Cold Room Operation:

- t_m at 250 rpm at 4 °C = 12 minutes

The total system operating time at 4°C was three days, which did not adversely impact the system or the electronics. The mixing time reported is for 1X PBS buffer components in the cold room after the three-day exposure period.

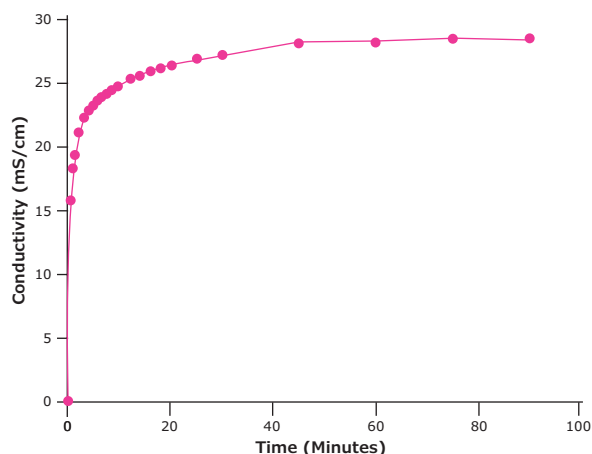


Figure 4. Conductivity vs. Mixing Time at 82 cP and 24°C at 250 rpm

Recommended General Protocol

The mixing studies documented in this report were completed by first adding the total volume of water and then adding any required components. This was performed to evaluate the mixing system's ability to process the total liquid volume. A generic procedure for the use of the mixing system is stated below.

Generic Mixing Protocol:

1. Weigh out water or starting solution to approximately 25% to 50% of the final target

2. Set impeller speed to 250 rpm or validated mixing speed
3. Add the solid- or liquid-phase ingredients and continue mixing between additions of each component
4. Add sufficient quantity of the water or starting solution to 98% to 100% of the final target. pH or other measurements may be required before the final quantity is determined

Discussion

Based on this characterization work, the Mobius® MIX500 system is capable of handling a variety of liquid-liquid and solid-liquid mixing applications. The information presented in this technical brief can be used as a reference for various mixing applications. However, we recommend that all specific applications be evaluated prior to implementation. Contact your local Applications Specialist for assistance with any Mobius® process solution.

References

1. Mobius MIX200 Disposable Mixing System Application Note (AN1274EN00)
2. Mobius MIX100 Characterization Technical Brief (TB1701EN00)

For more information, please visit
[MerckMillipore.com](https://www.MerckMillipore.com)

