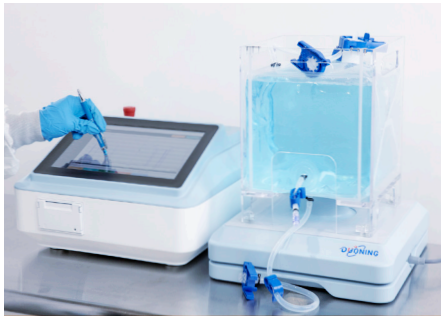
Powder-Liquid Mixing Characterization Using Duoning Mixers

SINGLE-USE MIXING

The DuoMixer® and the MiniDuoMix® are advanced single use mixers designed for mixing applications such as media and buffer formulation, intermediate processing, drug substance purification, and drug product formulation. Both mixers utilize a high performance magnetically driven impeller system that is fast and powerful for effective mixing of powders and viscous products. The systems can be used in combination with Duoning 3D single-use mixing bags, to eliminate cleaning time and improve efficiency.

3" OR 4" PORT FOR POWDER ADDITION

DUOMIX® 15" HMI TOUCHSCREEN



MINIDUOMIX® WITH HMI TOUCHSCREEN

MIXING STUDY

Mixing studies were performed on the 100L DuoMixer® and 20L MiniDuoMix® to quantitatively evaluate the mixing performance of each mixer. The mixers were challenged with formulations representing varying difficulties of powder to liquid mixing scenarios. 0.1M NaOH, 3M NaCl, and 5M NaCl represented easy, medium, and difficult mixing scenarios respectively. Compendial grade chemical reagents were used for all testing performed and twelve runs were conducted in total. The chemical quantity added, duration of chemical addition, duration of mixing periods, impeller RPM, starting and ending temperature, and in-line conductivity measurements were recorded.

The following sequence of operations was followed for the conducted mixing studies: Chemicals were weighed out and segregated, water was added to the mixing vessel and the agitator was brought up to the required RPM. The first half of the chemicals were added to the mixer at a constant rate and allowed to mix until clear. The next quarter was then added more slowly at a stable rate and again allowed to mix until clear. The final quarter of the chemicals were added in the same manner and the solution was allowed to mix until all chemical additions were fully solubilized and the conductivity measurements had stabilized. The end of mixing was constituted by the solution conductivity reaching within 3% of the final conductivity target. All studies were performed with water at 23°C ±1°C. **The data gathered was used to generate the values listed in Figure 1 below.**

				TIME TO MIX (MIN)		
MIXER MODEL	VOLUME RATIO	VOLUME (L)	RPM	0.1M NaOH	3M NaCl	5M NaCL
MiniDuoMix®. 20L	1:1	20	500	10.1	10.0	11.8
MiniDuoMix®. 20L	1:5	4	325	12.2	16.4	23.5
DuoMixer® 100L	1:1	100	300	9.2	12.7	12.4
DuoMixer® 100L	1:5	20	75	10.2	15.5	15.0

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MiniDuoMix® Mixing Study

Six powder to liquid runs were performed in evaluation of the 20L MiniDuoMix®. This mixer utilizes an acrylic bag holder designed for benchtop use. The maximum working volume of 20L was tested at 500 RPM while the minimum working volume of 4L was tested at 325 RPM. The impeller types used were P-4 angled blades with an impeller power number of 1.25. The graphs in figures 2a, 2b, and 2c show the conductivity in mS/cm throughout mixing.

Figure 2a.

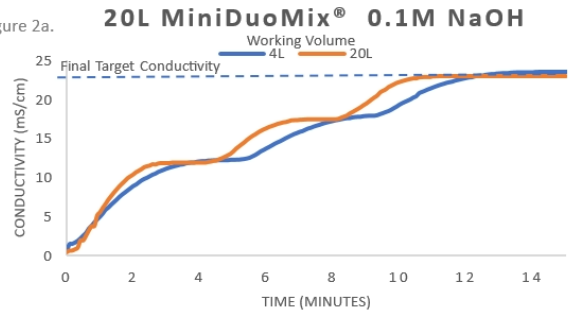


Figure 2c.

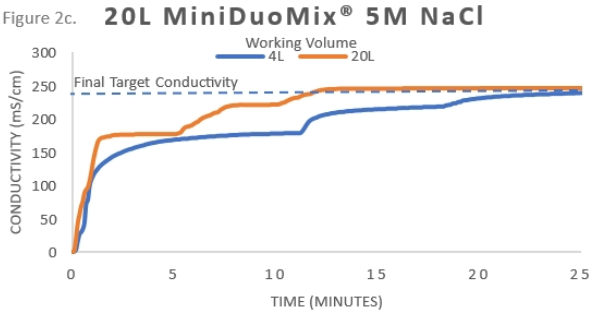
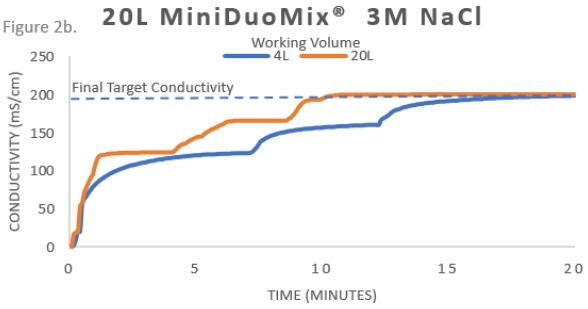


Figure 2b.



DuoMix® Mixing Study

Six powder to liquid runs were performed in evaluation of the 100L DuoMixer®. This mixer utilizes a jacketed 304 stainless-steel body capable of heating or cooling. The maximum working volume of 100L was tested at 300 RPM while the minimum working volume of 20L was tested at 75 RPM. The impeller types used were S-4 rushton style blades with an impeller power number of 6.76. The graphs in figures 3a, 3b, and 3c show the conductivity in mS/cm throughout mixing.

Figure 3a.

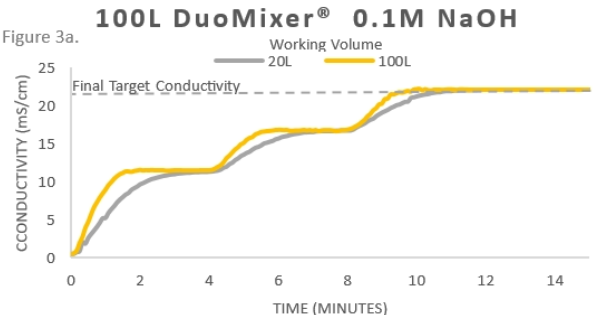


Figure 3c.

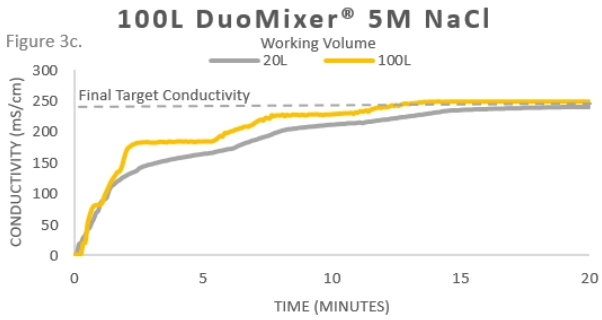
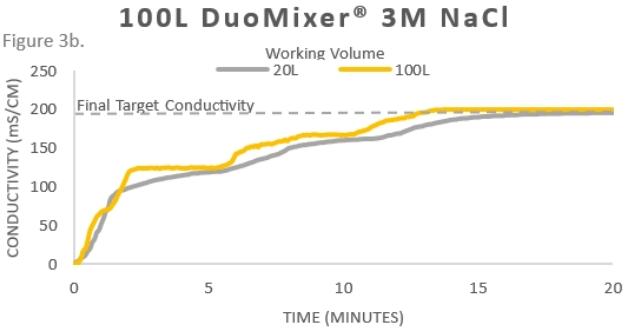


Figure 3b.



Study Conclusions

Duoning mixing systems are a suitable and efficient solution for powder-liquid mixing. Organizations can successfully implement the MiniDuoMix® or DuoMixer® for a reliable single-use mixing process, realizing benefits in terms of time and efficiency.

Testing was performed by bioX LLC (bioxeng.com) at their Bioprocess Applications Testing Laboratory in Salem, NH. bioX is an independent third-party specializing in single use materials and equipment testing intended for use in the cGMP Manufacturing. All data was generated under controlled laboratory conditions in compliance with a quality management system utilizing NIST traceable measurement devices and standards.