

Powder-Liquid Mixing Characterization Using FlowMixer™

SINGLE-USE MIXING

The FlowMixer™ is an advanced single use mixer designed for mixing applications such as media and buffer formulation, intermediate processing, drug substance purification, and drug product formulation. FlowMixer™ utilizes a high performance magnetically driven impeller system that is fast and powerful for effective mixing of powders and viscous products. The system can be used in combination with FlowLinX® 3D single-use mixing bags, to eliminate cleaning time and improve efficiency.



FLOWMIXER™ WITH HMI TOUCHSCREEN



WEIGHING MEASUREMENT & CONTROL VIA LOADCELL

MIXING STUDY

Mixing studies were performed on the FlowMixer™ to quantitatively evaluate the mixing performance of each mixer. The mixer was 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. Compensial 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.**

MIXER MODEL	VOLUME RATIO	VOLUME (L)	RPM	TIME TO MIX (MIN)		
				0.1M NaOH	3M NaCl	5M NaCl
FlowMixer™ 20L	1:1	20	500	10.1	10.0	11.8
FlowMixer™ 20L	1:5	4	325	12.2	16.4	23.5

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FlowMixer™ Mixing Study

Six powder to liquid runs were performed in evaluation of the 20L FlowMixer™. 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 20L FLOWMIXER™ 0.1M NaOH

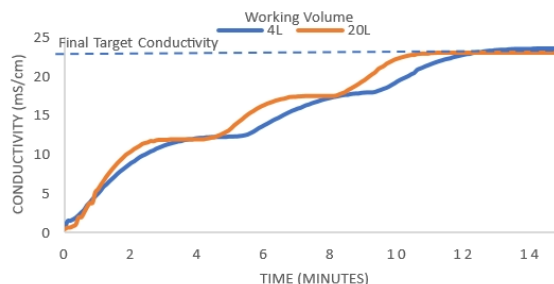


Figure 2b 20L FLOWMIXER™ 3M NaCl

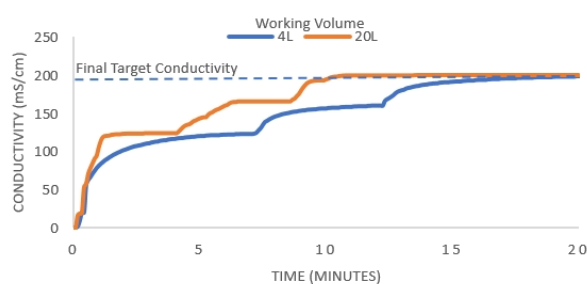
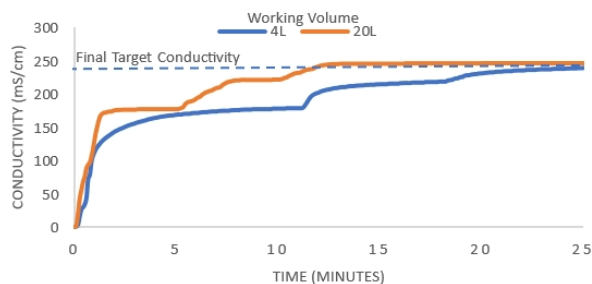


Figure 2c 20L FLOWMIXER™ 5M NaCl



Study Conclusions

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

Testing was performed by bioX LLC (bioeng.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.