Mixing efficiencies for the 100 L HyPerforma Single-Use Mixer

Goal

The next-generation Thermo Scientific™ HyPerforma™ Single-Use Mixer (S.U.M.) provides enhanced functionality, ease-of-use, and efficiency for critical up- and downstream process liquid preparation. In this study, the 100 L HyPerforma S.U.M. was tested to demonstrate its mixing efficiency.

Materials and methods

To demonstrate mixing efficiency across the workflow, four separate mixing materials representing buffers, classical media, and specialty media (Table 1) were used at both the nominal volume (100 L) and at the minimum turndown ratio (20 L).

Table 1. Mixing studies performed on the 100 L S.U.M.

Mixing study material	Solution concentration	Analytics
Sodium chloride*	1 M	Osmolality, conductivity
RPMI medium*	1X	Osmolality, glucose concentration
Gibco™ CD OptiCHO™ AGT™ medium	1X	Osmolality, glucose concentration
Glycerol	10%	Osmolality, specific gravity

* 100 L studies were done in duplicate

A standard 100 L S.U.M. and custom bioprocess containers (BPCs) with sampling ports located at the top, middle, and bottom of the unit were used. For the 20 L studies, only two sample points were used at the top and bottom of the volume.

The agitation speed for 100 L studies was set to 330 rpm (approximately 95% of maximum agitation speed) and for 20 L studies at 150 rpm (recommended for this volume).

The powder or liquid for each study was added directly to the top of the mixer. To represent a worst-case scenario, agitation was not initiated until all of the powder or liquid was added.

Each mixing study was done in an hour; where 25 mL (+/- 5 mL) samples were taken from each level with the following procedure:

- Mixing study materials were added 5 to 10 seconds prior to agitation and sample collection.
- First 10 minutes, samples were collected at 1-minute increments including time 0.
- Next 20 minutes, samples were collected at 5-minute increments.
- Last 30 minutes, samples were collected at 10-minute increments.
- Each sample was analyzed at a later time.

Data was normalized based on the results from the last 10 minutes of each study.

Results

Sodium chloride (1 M)

Osmolality and conductivity studies were performed for the 20 L and 100 L volumes. Samples taken from the respective locations on the S.U.M. were averaged. Within 2 minutes, the osmolality (Figure 1) reached homogeneity for both volumes. The conductivity study (Figure 2), reached homogeneity at the 1-minute time point.

RPMI medium (1X)

Osmolality and glucose concentration studies were performed for the 20 L and 100 L volumes. Samples taken from the respective locations on the S.U.M. were averaged. Within 3 minutes, the osmolality (Figure 3) and the glucose concentration (Figure 4) reached homogeneity for both volumes.

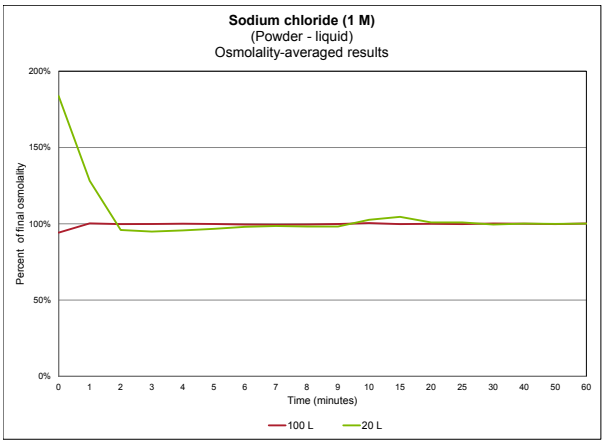

Figure 1. The average osmolality results of sodium chloride (1 M) for both the 20 L and 100 L volumes.

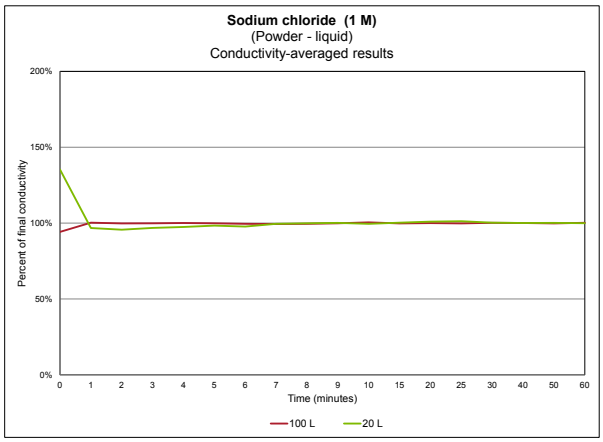

Figure 2. The average conductivity results of sodium chloride (1 M) for both the 20 L and 100 L volumes.

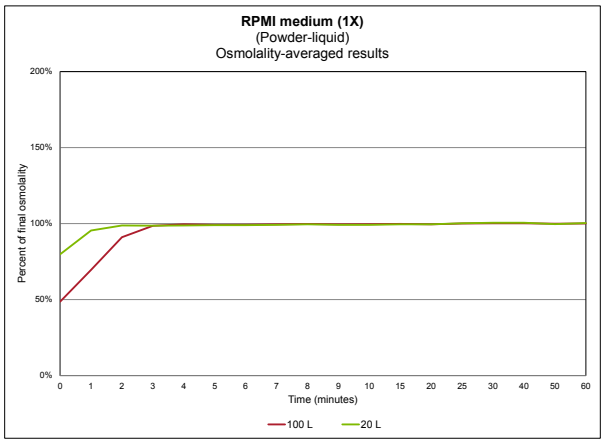

Figure 3. The average osmolality results of RPMI medium (1X) for both the 20 L and 100L volumes.

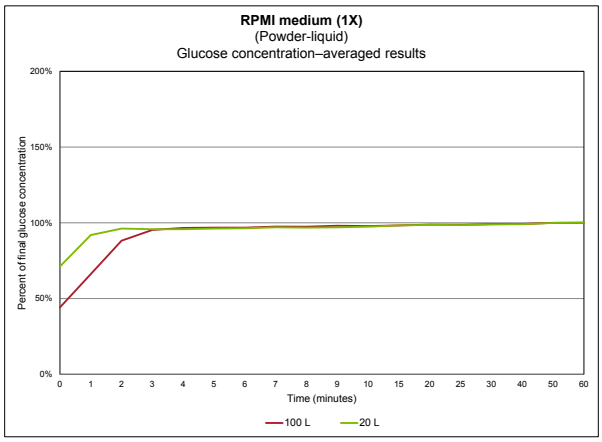

Figure 4. The average glucose concentration results of RPMI medium (1X) for both the 20 L and 100 L volumes.

CD OptiCHO AGT medium (1X)

Osmolality and glucose concentration studies were performed for the 20 L and 100 L volumes. Samples taken from the respective locations on the S.U.M. were averaged. For both osmolality (Figure 5) and glucose concentration (Figure 6) studies, the 20 L sample reached homogeneity within 1 minute and the 100 L sample reached homogeneity within 5 minutes.

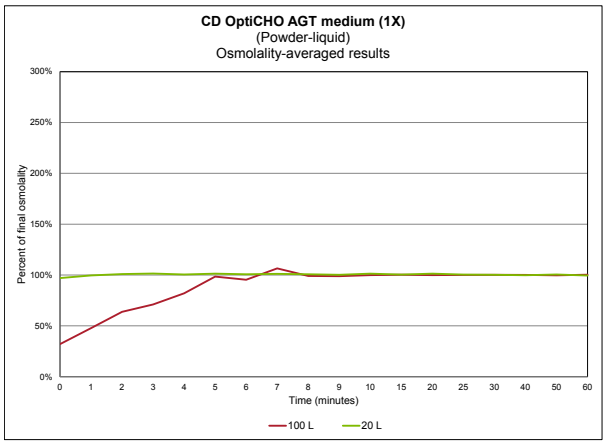

Figure 5. The average results of CD OptiCHO AGT medium (1X) for both 20 L and 100 L volumes.

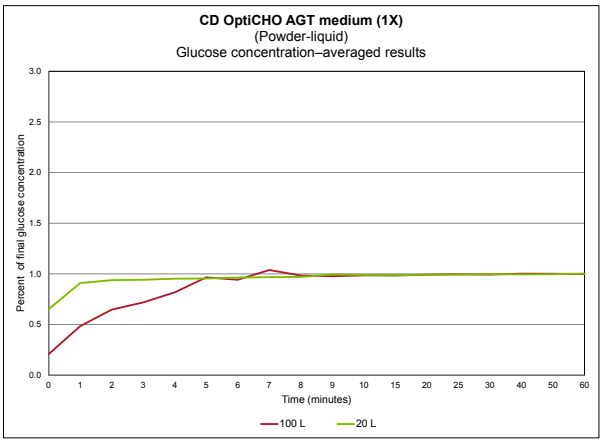

Figure 6. The average glucose concentration results of CD OptiCHO AGT medium (1X) for both the 20 L and 100 L volumes.

Glycerol (10%)

Osmolality and specific gravity studies were performed for the 20 L and 100 L volumes. Samples taken from the respective locations on the S.U.M. were averaged. Within 2 minutes, the osmolality (Figure 7) and the specific gravity (Figure 8) reached homogeneity for both volumes.

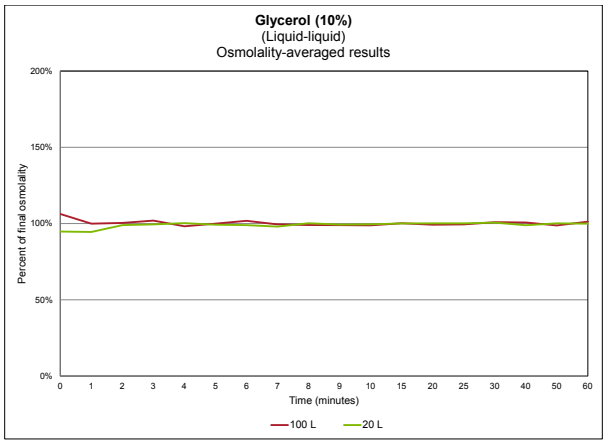

Figure 7. The average osmolality results of glycerol (10%) for both the 20 L and 100 L volumes.

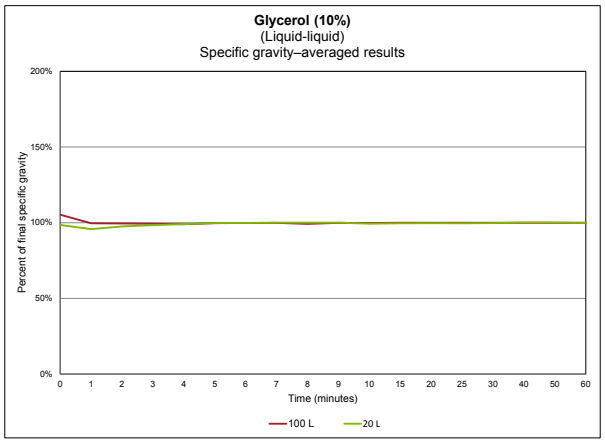

Figure 8. The average specific gravity results of glycerol (10%) for both the 20 L and 100 L volumes.

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Conclusions and recommendations

The 100 L HyPerforma Single-Use Mixer performs consistently within the specifications of our mixing systems from 5:1 to nominal volumes. The 100 L S.U.M. is capable of homogeneous mixing of typical powder to liquid and liquid to liquid materials within 5 minutes (Table 2).

Table 2. Average mixing time of 20 L and 100 L volumes using the 100 L S.U.M.

Mixing study material	In-solution time
Sodium chloride	1 to 2 minutes
RPMI medium	2 to 3 minutes
CD OptiCHO AGT medium	4 to 5 minutes
Glycerol	1 to 2 minutes

These studies represented a worst-case scenario, where the agitation was not started until all of the mixing study materials had been added. For typical use, it is recommended that the operator fill up to 80% of the desired volume with process water, enable the mixer, and set the agitation speed. Then over 5 minutes, add either powders or liquids to the top of the S.U.M. with a total mixing time of 10 minutes.

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