Oceo Rover - An Automated Media Hydration System

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INTRODUCTION

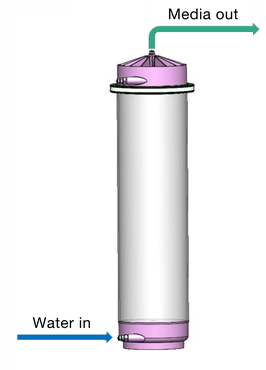
Biopharmaceutical manufacturers are facing increased pressure to be faster to market, while reducing costs and without compromising patient safety. There has been optimization throughout the upstream and downstream processes, resulting in more efficient and productive facilities. Although, one part of the biopharmaceutical manufacturing process has been overlooked. As a supporting process, the production of media, feeds, and buffers from stock powder has been neglected as an area for optimization, and as such, it has now been recognized as a major source of inefficiency. To identify specific problems, a survey of 24 large-scale biopharmaceutical manufacturers was performed. Here are the problems they identified that stem directly from the currently accepted methods of media preparation:

- Labor intensive process
- Mixing and dissolution of powders
- Time consuming
- Causes bottlenecks
- Uniformity of mixing
- Economics of media prep
- Environmental exposure
- Batch-to-batch consistency
- Sterility

FUJIFILM Irvine Scientific developed a solution to address these issues - the Oceo Rover, an automated hydration solution for media feeds and buffers. The components that make up the Oceo Rover include:

- Human Machine Interface **(A)**
- Primary Hydration Cartridge **(B)**
- Single-use Manifold **(C)**
- Secondary Hydration Cartridge **(D)**

The Oceo Rover hydrates media by directing the flow of water through the primary and secondary hydration cartridges.The components of the powdered media are split between the primary and secondary hydration cartridges to ensure the correct hydration. Water enters the bottom inlet of the cartridge and hydrated media flows out of the top of the cartridge.



OBJECTIVE

The purpose of this study is to prove equivalence, consistency, and efficiency of the Oceo Rover compared to conventional media preparation systems. This poster compares 12X IMDM runs in the Oceo Rover to conventionally-prepared IMDM. IMDM was chosen for this study because it's formulation is published, and therefore amino acid and vitamin data, normally considered proprietary, could be shared.

RESULTS

The Oceo Rover's functionality provides equivalent hydration performance with enhanced reproducibility and consistency in less time.

AMINO ACID AND VITAMIN ANALYSIS

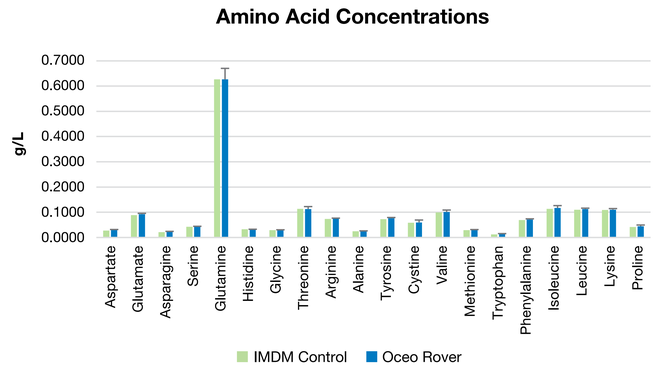


Figure 1. Amino acid levels meet release criteria. The data presented here represents 12 runs in the Oceo Rover versus 1 control run of liquid IMDM.

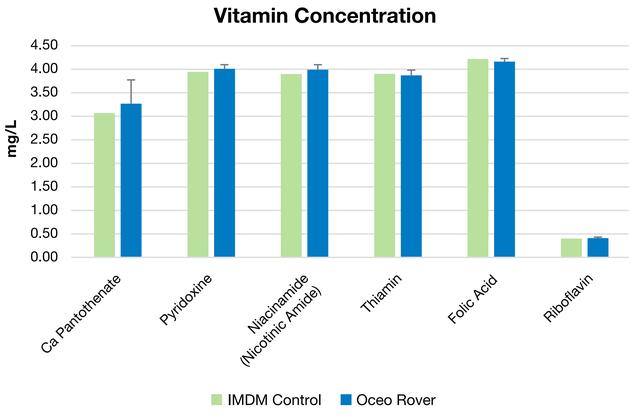


Figure 2. Vitamin levels meet release criteria. The data presented here represents 12 runs in the Oceo Rover versus 1 control run of liquid IMDM.

pH AND OSMOLALITY

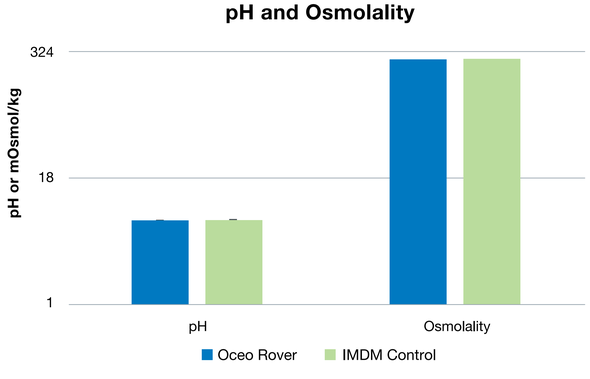


Figure 3. The pH and osmolality meet release criteria. The data presented in this graph is from 12 Oceo Rover runs and 6 manufacturing runs of IMDM.

CONSISTENCY OF PROCESS RUNS

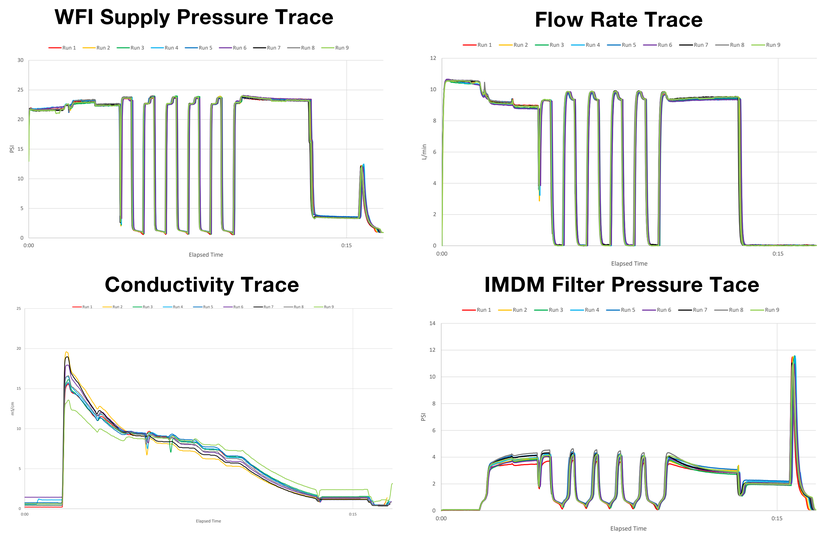


Figure 4. WFI supply pressure, flow rate, conductivity, and filter pressure traces were reproducible for nine 100 L Oceo Rover batches. The consistency of the Oceo Rover process leads to a more consistent product.

MEDIA HYDRATION TIME

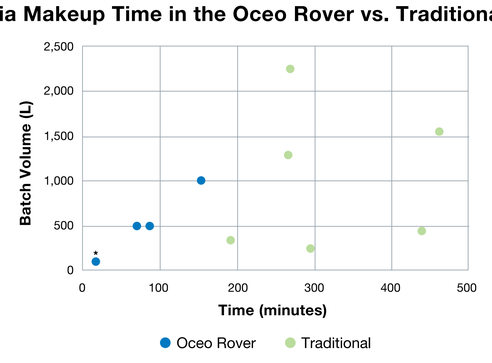


Figure 5. 100 L IMDM runs (n=9)* were performed in the Oceo Rover and each took 17 minutes. One 500 L Oceo Rover run was performed and took 1 hour and 30 minutes, and a second 500 L run was performed with an optimized automation recipe that only took 1 hour and 10 minutes. The 1,000 L Oceo Rover run took 2 hours and 30 minutes. 6 IMDM manufacturing runs from 247-2,250 L were evaluated and took 3-8 hours. The runs performed in the Oceo Rover had more consistent production times batch-to-batch than the manufacturing runs. The 1,000 L Oceo Rover run was significantly quicker than the 3 manufacturing runs that were less than 500 L volumes.

CONCLUSIONS

The Oceo Rover produces equivalent media in a more consistent and shorter time (100 L in an average of 17 minutes, comparatively 2-fold to 5-fold faster) compared to manual media preparation and uses fewer resources when compared to conventional stainless steel or single-use systems. The Oceo Rover provides flexibility and efficiency to the media and buffer hydration process, delivering consistent solutions on demand.

1. Powder Culture Media Packaging. Preparation and Market Trends. BioPlan and Associates, Inc. (2014)