FUJIFILM Biosciences

Oceo Rover: A Versatile and Scalable Solution for On-demand Process Liquid Hydration

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INTRODUCTION

The biopharmaceutical industry is continually under pressure to increase production and decrease costs, with a focus on optimizing core upstream (USP) and downstream (DSP) processes. Both USP and DSP rely on process liquids that are hydrated from powders at large scale. The hydration of process liquids has always relied on the use of mixers, either single-use or fixed systems. Therefore, this has not been seen as an area to optimize processes for cost or quality improvements; it has been accepted as the way we have always done it.

Oceo Rover, by FUJIFILM Biosciences, is the first and only automated single-use hydration system designed specifically for media feeds and buffers. The Oceo Rover can hydrate solutions for both USP and DSP, providing versatility as only one Oceo Rover system is needed to hydrate different volumes and concentrations. Gone are the days where mixers of various sizes line the hallways of your manufacturing suites.

The purpose of this study is to demonstrate the predictability and versatility of the Oceo Rover in hydrating a wide variety of powders, as well as its capability to produce a broad range of volumes. The formulations were developed by our R&D team, leveraging the Oceo Rover's advanced technology to optimize the hydration of process liquids.

MATERIALS AND METHODS

The components that make up the Oceo Rover include:

A- Human Machine Interface (HMI)
B- Primary hydration cartridge
C- Single-use manifold
D- Secondary hydration cartridge

The Oceo Rover hydrates powders by directing water through the primary cartridge, via either the bottom or top inlet. A secondary cartridge is available, usually used for media formulations, where components that don't hydrate readily in water reside. Water enters through an inlet on the cartridge and hydrated process liquids flow out of the top outlet of the cartridge. Its ability to hydrate both media and buffers at various concentrations makes it a versatile and scalable way to hydrate your process liquids quickly.

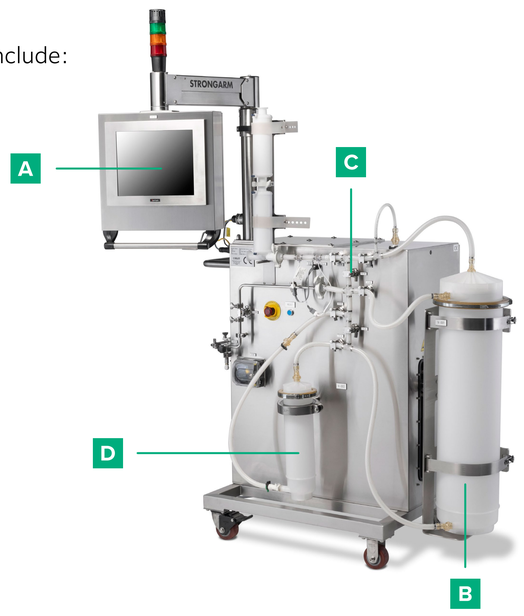

Figure 1. The Oceo Rover Automated Hydration System.

Beyond the flow of water through the cartridge, the Oceo Rover has other features that assist with the hydration of powders:

Pulsation: Used for media hydration. Cuts the water supply to the cartridge, therefore dropping the pressure in the primary hydration cartridge; allowing clumps of undissolved powder to break apart.

Recirculation: Used for highly concentrated solutions such as feeds or buffer concentrates.

Recipes were designed by our R&D team, utilizing the many features of the Oceo Rover to hydrate the process liquids.

Media:
- BalanCD CHO Growth A - Powder (Catalog # 94120)
- BalanCD CHO Feed 4 - Powder (Catalog # 94134)

Buffers: Enables production of a wide range and volume of upstream and downstream buffers.

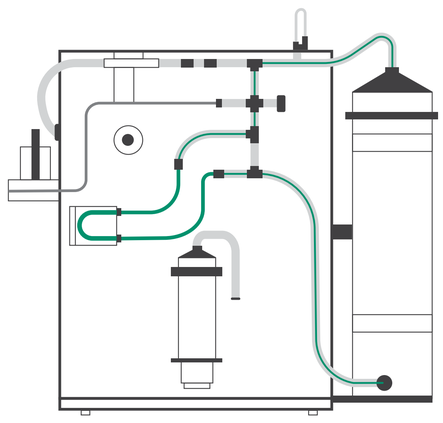

Figure 2. Flow path for recirculation on the Oceo Rover.

EFFICIENCIES

Oceo Rover

- Hydrate and sterile filter in a single unit operation
- Simple LOAD. SET. GO. methodology

Resulting in

- Reduced production times
- Consistent solutions on demand
- Ready-to-use material, no adjustments required

Delivering

- Predictable outcomes
- Greater operational flexibility
- Higher facility utilization

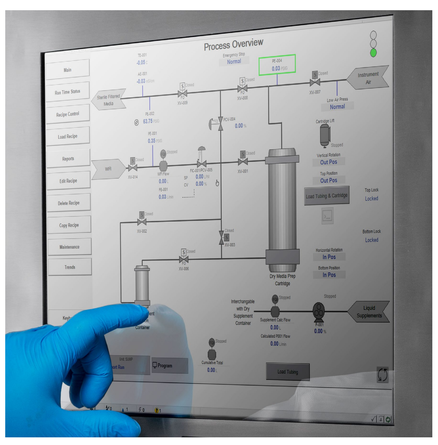

Figure 3. Oceo Rover HMI.

RESULTS

Buffers

Table 1. Average time to hydrate NaCl in the Oceo Rover.

Concentration	Weight (kg)	Volume (L)	Time (Minutes)
0.5 NaCl	14.610	500	64
1.5 M NaCl	17.532	200	33
3 M NaCl	17.532	100	25
3 M NaCl	58.198	332	61
4 M NaCl	35.064	150	76
4.5 M NaCl	39.447	150	84.5

Various volumes and concentrations of NaCl were hydrated. The concentrations and volumes hydrated are provided in **Table 1.**

Table 2. Buffers that have successfully been hydrated in the Oceo Rover multiple times and at different volumes and concentrations.

Types of Buffers Produced	Concentration	Volumes Hydrated (L)
NaH_2PO_4	0.02–2 M	100–150
Na_2HPO_4	0.1–0.3 M	50–150
NaOH	0.5 N	100–600
NaCl	0.5–4 M	100–500
Tris HCl	1.6 M	50
Citrate NaCl	100 mM	100–400
$NaPO_4$	50–100 mM	100–1,000
Na HEPES	1 M	100
$NaPO_4$ NaCl	20 mM, 150 mM; 20 mM, 500 mM	200–1,000
Glucose	25%	120
$NaPO_4$ NaCl KCl	250 mM, 100 mM, 50 mM	150
Tris Base	2 M	100
Na Tyrosine	300 mM	180
Ammonium Sulfate	3–4 M	80–100
Tris Buffer	3 M	100
$NaPO_4$ Ammonium Sulfate	3 M	100

This is not a comprehensive list of what can be hydrated in the Oceo Rover, but shows the variety of solutions that can be produced. All of the above solutions were made in less than 2 hours.

Media

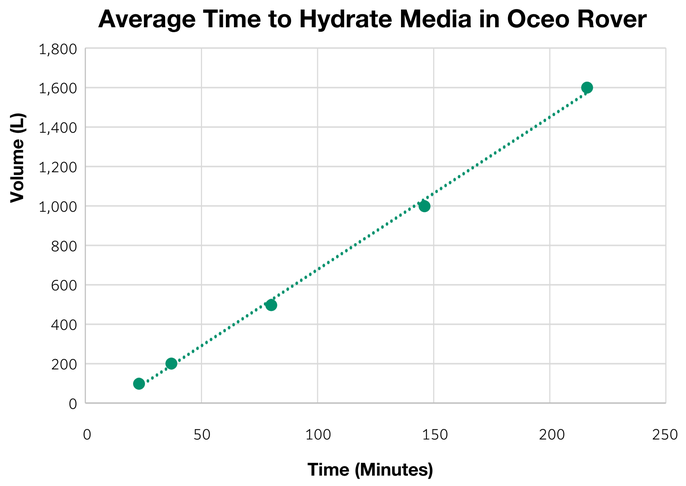

Figure 4. Average time to hydrate cell culture media in the Oceo Rover. The time it takes to hydrate BalanCD CHO Growth A in the Oceo Rover is predictable and has a linear relationship between volume made and time to hydrate the media.

Table 3. The average amount of time to hydrate cell culture media in the Oceo Rover (shown in Figure 4).

Volume (L)	Average Time to Hydrate (Minutes)
100	23
200	37
500	81
1,000	149
1,600	237

Table 4. The average amount of time to hydrate feed media in the Oceo Rover.

Volume (L)	Average Time to Hydrate (Minutes)
100	69

Feed media is more concentrated, as a result smaller production volumes are made. Oceo Rover supports this production.

SUMMARY

Oceo Rover supports biomanufacturing by delivering consistent solutions on demand utilizing prefilled cartridges, which include but are not limited to:

- Phosphate buffers
- Citrate buffers
- Tris buffers
- Growth media
- Feed media

The Oceo Rover enables scalable and predictable media hydration from 100 L to 1,700 L and buffer hydration from 100 L to 5,000 L.