

CHO clarification of a 1000 L SUBs in less than 6 hours with UniFuge[®] Single Use Centrifuge. <u>David</u> <u>Richardson, Pneumatic Scale Angelus, Clearwater, 33760, USA</u> <u>david.richardson@psangelus.com</u>

Introduction: In this study, we will clarify two Cho Batches with a single use centrifuge. The first batch is a 1000 liters of CHO cell culture broth @ 70% viability and 13.10⁶ cells/ml (3% PCV). 50 liters feed/discharge cycle. The second batch is a1000 liters CHO cell culture Broth @ 23 % viability (PCV 3.6 %). We will process 42 liters feed per discharge cycle.

Experiment: The Centrifuge Equipment is a tube bowl centrifuge called the UniFuge[®] Centrifuge manufactured by (PneumaticScale Angelus). The insert is a single use module with a 4 tubes set.

The experimental Parameters are as follows: G force: 3000 x G, 4000 x G at bowl wall.

Feed flow rate: 1-6 Lpm, feed process time. The Centrifuge is operating in automatic mode. The cooling jacket is set to 7° C.

The process Method

Batch one: Fill bowl with 50 liters of feed to 89 % capacity or 1.5 liter of pellet. Batch two: Fill bowl with 33 liters of feed to 70 % capacity or 1.2 liter of pellet. Once the bowl is fed, discharge bowl.

| G force/viability | Feed rate LPM | Ntu | Pmax (rated- 1 best) |
|-----------------------|---------------|---------|-----------------------|
| 3000 / 70% | 2 | 80 | |
| Control 1260 | | | |
| 3000 | 3 | 94 | |
| 3000/4000 | 4 | 111/102 | |
| 3000/4000 | 5 | 120/115 | |
| 3000/4000 | 6 | 144/118 | |
| 3000/4000 | 1 | 70/72 | |
| 4000 23% Control>1000 | 1 | 50 | 1 |
| 3000 | 3.4 | 63 | 4 |
| 4000 | 3.4 | 71 | 3 |
| 4000 | 6 | 82 | 2 |

Results:

Conclusion: The UniFuge[®] is an effective tool for clarification of CHO.

The feed flow rate of up to 6 lpm allows it to be used in large scale SUB production. At 70% viability, the total process time for a 1000 liter SUB is 246 minutes with 20 discharges. At 23% viability is 286 minutes with 24 discharges. The low shear inlet and no shear discharge mechanism allows the elimination of cells and debris is proven with low NTU. Centrifuge centrate Pmax was 2x that of disk stack – approx. 400 L/m². The single use module weighs 1 KG compare to wet and heavy filtration cartridges.