Success – Optimizing Bioburden Reduction Filtration of Saline Solutions

CRITICAL PROCESS FILTRATION, INC.

Description of the Filtration Challenge

A pharmaceutical manufacturer was evaluating their bioburden reduction filtration of various saline solutions to improve throughput and cost per liter. Critical Process Filtration was asked to provide filters for tests in the customer solutions. Comparative testing was initially done at laboratory scale with the filter currently used and alternative designs from Critical Process Filtration.

The challenges were:

- The solutions have high levels of undissolved solids
- The preservative solution intermittently caused filter fouling
- The filters could not affect levels of active ingredients

Comparative Testing at the Critical Process Filtration Application Laboratory

Our Technical Service team performed bench testing of throughput for filtration options using a surrogate saline solution with undissolved inorganic particles. The results were compared to the performance of a dual layer, blended cellulose acetate membrane filter option, which was the filter in place at the customer facility.

Screening tests were done using disc filters. The solution was fed through the filter discs at a constant flow rate, and the volume filtered recorded once a terminal pressure drop value was reached.

Several filter media were tested in this field trial:

1. Single Layer Polyethersulfone (PES) Membrane
2. Dual Layer PES Membrane
3. PES Membrane with High Capacity PES Membrane Prefilter
4. Dual Layer Blended Cellulose Membrane

Laboratory Test - Media Option Results:

The solution was passed through each media option individually to test throughput. At the end of the tests, the team recommended a filter using a PES membrane with high capacity PES membrane prefilter as the option most likely to have the highest throughput of saline solution with undissolved particles and a preservative that might blind the membrane.

Discussion

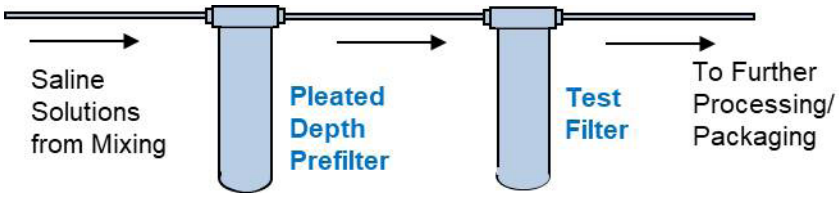
The high levels of undissolved solids means that a large number of particles needs to be captured by the filter. While a pleated depth prefilter will capture larger particles, the smaller particles that pass through a depth filter will blind a single layer membrane filter. Using a prefiltration layer in the membrane filter increases the particle holding capacity of the filter and significantly improves throughput.

On-Site Testing at the Customer Facility

The customer ordered a large quantity of High Capacity PES Membrane/PES Membrane filters to use in a full scale filtration test of production products.

The filters were tested in the production filtration system (see diagram below), which used a pleated depth filter as a prefilter in the process. The same type of prefilter was used for testing both the existing cellulose acetate filter and the filter from Critical Process Filtration.

Production Filter Train Used for Testing



Success Story

Customer Test - Results:

Testing was done on four saline solution products with different added ingredients. In all cases, the Critical Process Filtration filter with the high capacity PES membrane prefilter layer and PES membrane final filtration layer outperformed the dual layer cellulose acetate filter. The table below shows the increase in throughput using the Critical Process Filtration filters.

Saline Solution	Increase in Throughput Using Critical Process Filtration Filter
Product 1	+42%
Product 2	+88%
Product 3	+35%
Product 4	+51%

Improved Performance and Lower Cost per Unit

Each saline solution had a unique mix of active ingredients and level of undissolved particles. With the higher throughput, the cost per unit of final product dropped an average of almost 14%.

Customer Quality Testing

The filtrates from the full scale filtration tests were tested by the customer according to their established test protocols. All solutions showed that levels of organisms and other contaminants were well within specifications. The filtrate after both the existing filters (blended cellulose) and the PES Membrane/high capacity PES membrane filters showed that all active ingredient concentration and activity results were within product specifications.

Conclusion

The customer switched to using the PES Membrane/High Capacity PES Membrane filter for all saline solutions. The filter chosen was a Biopharmaceutical Grade PES filter (BPS) with a 0.22µm PES membrane final filter layer and a 0.5µm high capacity PES prefilter layer.

Visit our website for more information on this and other applications and to access data sheets on all of our products, or contact us to ask one of experienced technical staff to help with a filtration challenge.

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