

Success – Increased Throughput and Reduced Processing Time for Upstream Filtration of Animal Serum



Description of the Filtration Challenge

An animal serum processing company was experiencing difficulty in filtering animal serum.

- Premature filter plugging leading to multiple mid-batch filter changes and resulting product loss.
- Long processing times - up to 48 hours to process a 30 liter batch.
- Reappearance of gels after filtration.

Process Evaluation

Our Technical Service team reviewed the filtration process.

- The amount of gels in the serum varied from batch to batch .
- The process could be improved by pre-screening through a 100 micron strainer or decanting the serum from the gels
 - Both of these options were impractical at full scale.
- The customer was using four different filters, one step at a time.
- Filters from different suppliers were used in the individual steps without formal research on how well the filters worked together – a possible source of inconsistent performance and results.

Filterability Testing

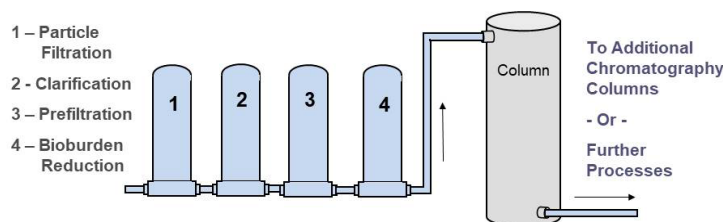
The customer sent a serum sample to Critical Process Filtration for testing in our Applications Lab.

- The first step was to identify a first stage filter – Particle Filtration - that could process a 30 liter batch without screening or decanting. Three media were tested using 47 mm discs. Both constant flow and constant pressure tests were performed to predict the expected throughput for a 10-inch filter. The results are shown in the following table.

Media Material	Pore Size	Projected Volume (for 10-inch filter)
Polypropylene Flat Sheet Depth	1 μm	7 liters
Fiberglass Flat Sheet Depth	1 μm	33 liters
Fiberglass Flat Sheet Depth	1 μm	65 liters

- Similar testing was performed using the pre-filtered serum to identify appropriate filters for Clarification, Prefiltration and Bioburden Reduction steps which would allow processing 30 L through a single 10-inch filter.
- The optimized filter steps were identified as:
 1. Particle Filtration: 10 μm Fiberglass
 2. Clarification: 1 μm Fiberglass
 3. Prefiltration: 1 μm Polypropylene Depth
 4. Bioburden reduction: 0.22 μm or 0.45 μm Polyethersulfone (PES) membrane

Figure 1 - Upstream Filtration in Serum Processing



Serum processed using the above filtration sequence showed no signs of gel reappearance after three weeks of storage at 4°C.

NOTE: Although the data from the first step testing showed the 1 µm Fiberglass might be acceptable as the first stage filter, due to the variability of gel content in the serum, the 10 µm was recommended.

Customer Site Testing

A Critical Process Filtration Technical Service team member visited the customer site to assist in implementation of the recommended filtration system, train personnel, and verify operation of the filter train.

- Personnel were trained on proper installation, operation, and monitoring of filters/housings.
- The customer was shown the benefit of placing filters in series, rather than performing four separate filtration steps.
 - Only two housings were available at the time, and a batch was successfully processed using 10 µm Fiberglass followed by 1 µm Fiberglass, then a second filtration step using 1 µm Polypropylene followed by 0.22 µm PES. The customer has since ordered additional filter housings toward setting up all four filters in-line.
- A batch with a lower level of visible gels was successfully processed without the 10 µm Fiberglass.
 - As a result of this second test, the our Technical Service team developed a “filterability test” using 47 mm disks of the 1 µm Fiberglass media and a small volume of serum that the customer could use to determine whether or not the 10 µm filter would be required.
- The Technical Service team provided written documentation on filter operation, reviewed the existing customer documentation with recommended revisions, and generated a written procedure for the filterability test.

Results

- The Customer has a repeatable filtration process that reduces batch processing time (less than a day for 30 liter batch) and minimizes product loss due to filter changes.
- All filters used come from a single supplier, ensuring consistent performance.
- The Customer has implemented the filtration train shown below, and has an in-process test to indicate the necessity of the 10µm Fiberglass.
 1. Particle Filter - 10µm Fiberglass Depth Filter (CPF Model “PGD10-” filters*)
 2. Clarification - 1µm Fiberglass Depth Filter (CPF Model “PGD1-0” filters*)
 3. Prefilter - 1µm Polypropylene Depth Filter (CPF Model “PPD1-0” filters*) (may be exchanged for smaller pore size depending on performance of final filter)
 4. Bioburden Reduction - 0.22µm or 0.45µm Polyethersulfone (PES) Membrane Filter (CPF Model “BPS-20-” or “BPS-40” cartridge filters*)

*Exact part numbers are based on filter length and end adapters chosen. See product data sheets for ordering information.

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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