

TANGENTIAL FLOW FILTRATION AND SCALABILITY FOR GENE THERAPY VIRUS PURIFICATION

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Pall Biotech has linearly scalable tangential flow filtration technology that can cover processing volume ranges from less than a liter to over 2000 liters. Manual assemblies can be used with Pall TFF filters in scales under 20L and programmable skids are available for larger scales. In this document TFF linear scalability of up to 200 liters is covered starting from a 7L initial volume and maintaining similar pressures, processing times and yields at all scales. Using this scalable technology Pall biotech can help biologics companies go to clinical trials and to commercial scale manufacturing successfully.

Column1	Small scale (~7L Clarified bulk)	Large Scale (~200L) Projected values
Processing time (concentration)	1hr 32 min	~ 1hr 30 min
Processing time (buffer exchange)	1hr 10 min	~ 1hr 20 min
Feed flow rate (concentration)	150 ml/min	190L/H (recommended)
Feed flow rate (buffer exchange)	150 ml/min	190L/H (recommended)
Membrane surface area	0.1 m ²	2.5m ²
Volume processed	7 L	~200
Titer (yield by qPCR)	1.51E+10 gc/cm ² or 100%	< similar
Flow decay	-47%	< similar
Cross flow flux (concentration)	99 LMH	< similar

