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#### **ACCEPTED MANUSCRIPT**

# Finding the design space of a filtration-based operation for the concentration of human pluripotent stem cells

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#### **Abstract**

Process knowledge for designing robust and reproducible unit operations is essential, especially for complex biological systems. This work describes a shortcut approach for the design of tangential flow filtration for the concentration of human induced pluripotent stem cells (hiPSC), supported by design of experiments. Critical process parameters (CPP) of shear rate, permeate flux and cell load were considered, and their impact on hiPSC recovery yield and viability was studied. A full factorial design confirmed significant interaction effects between all CPP, affecting both responses. The developed statistical model predicted that high shear rate (3000 s<sup>-1</sup>), permeate flux (250 LMH) and medium cell load (2 x 10<sup>6</sup> cell/cm<sup>2</sup>)

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