EVALUATION AND SCALE-UP OF SINGLE-USE BIOREACTORS FOR THE PRODUCTION AND HARVESTING OF A HEPATITIS C VACCINE CANDIDATE

Alex Xenopoulos, EMD Millipore
Alex.Xenopoulos@EMDMillipore.com
Lénaïg Savary, Merck Millipore
Ricardo Silva, iBET
João Clemente, iBET
Rute Castro, iBET
Sofia B. Carvalho, iBET
Mafalda Moleirinho, iBET
Paula Alves, ITQB-UNL/iBET
Manuel Carrondo, FCT-UNL/iBET
Cristina Peixoto, ITQB-UNL/iBET

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The present work examines the suitability of single-use bioreactors for production of a Hepatitis C Virus-Like Particle (VLP) vaccine candidate using the baculovirus expression system with Sf9 cells. It can be shown that a Mobius® 3L bioreactor results in viable cell concentration, viability, growth kinetics, stability and VLP production that are comparable to standard glass bioreactors. A simple translation of hydrodynamic working parameters between the two systems is adequate to match performance. Furthermore, we report on the successful scale-up of this disposable alternative from a 3L to a 50L scale using minimal optimization. These results demonstrate the potential and ease of use of this technology for the production of complex biopharmaceutical products. Using the 50 liters harvested from the run, we evaluated depth filtration and compared the results to centrifugation. Multiple filter trains with different properties were tested and the results on recovery, turbidity and impurity reduction will be presented and discussed.