

TESTA CHALLENGE 2024 PROCESS

Monoclonal antibody production as intermediate to ADC

The planned bioprocess operation for Testa Challenge 2024 is a monoclonal antibody (mAb) production to generate intermediate material for antibody drug conjugate applications. The process starts with establishment of a seed culture from frozen stock, continues with mAb production through a fed-batch process in a single-use bioreactor. Following cultivation, the cells will be removed from the culture via depth filtration and the resulting filtrate will be subjected to undergo two chromatography steps to purify the target protein.

Briefly, a vial of frozen cell bank will be expanded through several shake flask steps and finally in a ReadyToProcess Wave 25 unit as an N-1 bioreactor to generate a seed culture for the production stage. After a 4-day cultivation period in Wave, the stirred tank production bioreactor, an XDR-50 unit, will be filled with 28L ActiPro culture medium, and inoculated at a cell density of 0.5 M cells/mL. A fed-batch protocol will be implemented, utilizing ActiPro Cell Boost A & B together with a 40% glucose feed solution according to standard operating procedures. Following a 10-day period, the culture will be harvested by depth filtration utilizing the Pall Stax™ mAx depth filter clarification platform and subsequently it will be filtered through a 0.2 µm Pall Supor® EKV sterilizing grade filter as column guard prior to chromatography. The first chromatography capture step is utilizing 420 mL MabSelect PrismATM protein A chromatography resin packed in an AxiChrom 70 column. The second chromatography step will be performed on a 140 mL Capto adhere multimodal resin column in flow-through mode, resulting in the intermediate mAb which can potentially be used for drug conjugation experiments. Main quality attributes of the purified mAb will be determined by several analytical methods: aggregate content will be assessed via size exclusion chromatography; protein identity will be confirmed by RP-HPLC peptide map fingerprinting; and host cell protein content will be determined in an automated immunoassay using a Gyrolab xP workstation.

Questions? Do not hesitate to contact us!

We are more than happy to answer all your questions, please contact us at contact@testachallenge.com.

Testa Challenge 2024 is made possible thanks to:



KNIGHTEC

GYROS PROTEIN
Technologies

**RI
SE**

 Region Uppsala


TestaCenter
In collaboration with Cytiva