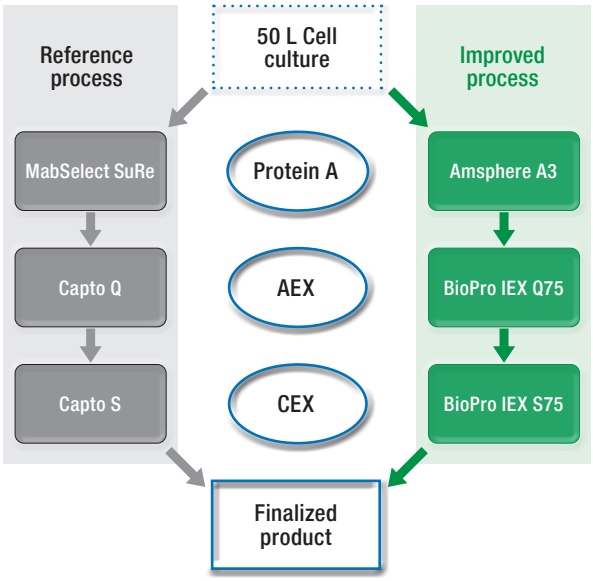
Technical Note

Efficient mAb Purification with BioPro IEX

Purification of a mAb from a 50 L CHO cell culture was studied under GMP conditions using BioPro IEX S75 / Q75 ion exchange resins. The achieved three-step process succeeded in producing mAbs with high purity and efficiency. Results were directly compared to those achieved with competitive IEX resins under identical conditions.

Process flow sheet

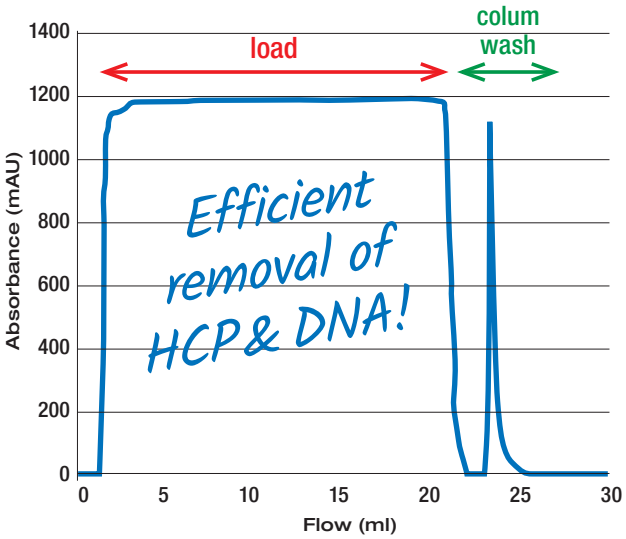
- Presented are the three-step reference and the improved process with regard to the involved resins
- Step 1: Affinity chromatography using Amsphere A3 resin of JSR Life Sciences for a first clean-up of the cell culture
- Step 2: Anion exchange chromatography via YMC´s BioPro IEX Q75 resin after dilution with 25 mM Tris-HCl buffer
- Step 3: Cation exchange chromatography using YMC´s BioPro IEX S75 as final polishing step
- An identical process sequence and identical experimental conditions ensured full comparability of the results



Anion exchange process conditions

- A highly efficient removal of HCP and DNA was achieved using YMC's BioPro IEX Q75
- An optimisation study was carried out to evaluate the pH influence on this step. Product yield and residual HCP concentration were constant between pH 8.0 and 9.0

-> robust & flexible process!



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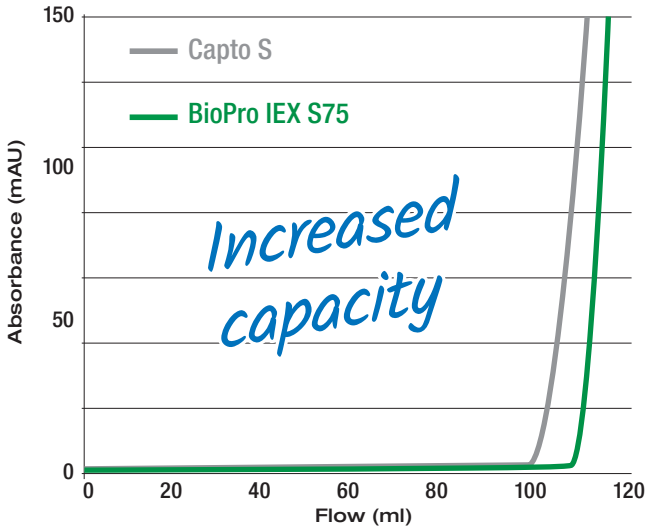
Cation exchange process conditions

- Presented are the DBC breakthrough curves of BioPro IEX S75 alongside a competitive resin
- An increased capacity is clearly visible and improves the efficiency of the overall process with a larger amount of product purified via each chromatographic cycle



Result summary

- The highly effective purification of the developed process is apparent
- YMC´s BioPro IEX resins are the ideal choice for efficient purification of mAb
- The AEX step was particularly effective in reducing residual impurities
- The CEX step succeeded as last step for polishing, in order to minimize remaining trace contaminations
- With 98.6% the process had a very high recovery of purified mAbs

Process step	HCP (ng / mg IgG)	DNA (pg / mg IgG)	mAb Monomer (%)
Cell culture fluid (Ref.)	127,000	66,900,000	–
Protein A capture	145	18,000	98.6
AEX	0.64	< 0.44	98.5
CEX	0.46	< 0.12	98.6

List of abbreviations:

mAb: Monoclonal antibody
CHO: Chinese hamster ovary
GMP: Good manufacturing practice
IEX: Ion exchange chromatography
AEX: Anion exchange chromatography
CEX: Cation exchange chromatography
HCP: Host cell protein
DNA: Deoxyribonucleic acid
DBC: Dynamic binding capacity

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