

Got Purification Troubles? Improve mAb Purification Process Efficiency with Mixed-Mode Resins



The Challenge

Does your monoclonal antibody (mAb) purification process have three steps? Are you trying to improve purity, yield, and process economics?



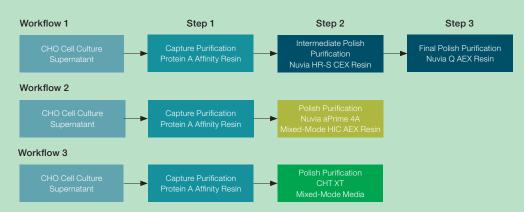
Purification Tip

Mixed-mode resins such as Nuvia aPrime 4A Hydrophobic AEX Resin and CHT™ Ceramic Hydroxyapatite XT Mixed-Mode Media can eliminate a purification unit operation, allowing you to obtain higher yield and comparable purity while saving time and money.



Our Approach

To evaluate the yield and purity of mAb purification by a traditional three-step process (workflow 1) and two-step processes (workflows 2 and 3), purification of a Chinese hamster ovary (CHO) cell-expressed trastuzumab biosimilar (pl 8.6) was performed.



Workflow	Step	Mode	HCP, ng/ml	Protein A, ng/ml	HCD, pg/μl	Monomer, %	Yield, %
All	Cell culture feed		4,252.0		90,348.9		
1	1	Bind and elute	196.6	10.5	1,879.5	96.1	>95
		Bind and elute			BDL	98.1	94.3
1	3	Flowthrough	3.0	4.1	BDL	99.2	97.1
		Flowthrough	BDL	0.2	BDL	99.0	
3	2	Bind and elute	3.5	0.1	0.15	99.0	>95

BDL, below detection limit; HCD, host cell DNA; HCP, host cell protein.

The results from the two-step processes demonstrate higher yield than the three-step process and comparable purity. The two-step processes removed leached Protein A twenty times more effectively than the three-step process. Additionally, host cell protein (HCP) and host cell DNA (HCD) removal is comparable across all three workflows, indicating that there is no compromise with the reduced number of processing steps.



^{*} Each workflow's leached Protein A concentration was determined only after the Protein A capture and final chromatography steps.

Innovative Products. Customized Solutions.

Nuvia aPrime 4A Resin

Nuvia aPrime 4A Resin delivers:

- A wide experimental design space
- Optimal product recovery
- Single-step removal of multiple impurities

Go to **bio-rad.com/NuviaaPrime4A** to explore the various features of Nuvia aPrime 4A Resin.

CHT Ceramic Hydroxyapatite XT Media

CHT XT Media will put you on the path to:

- Efficient, single-step clearance of impurities
- Great process economics (cost and time efficiency)
- Unique selectivity
- Straightforward column packing; also available as prepacked, process-scale Foresight Pro Columns

Go to **bio-rad.com/CHTXT** to explore the various features of CHT XT Media.

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- Method development
- Process development
- Column packing support
- Global technical support



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Nuvia aPrime 4A Resin is covered by U.S. Patent Number 9,669,402 and foreign counterparts.



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