

Affinity Separation powered by Nanofitins®

Nanofitins (NF)

7kDa affinity proteins

Process simplification and time reduction by introducing affinity in DSP



Tunable affinity ligands

- 100% in vitro selection process
 - Highly specific for the product, ensuring high purity
 - Mild elution condition, ensuring product integrity
 - Applicable to any biologics
 - NF binding pocket can be engineered to improve performance

Extremely robust

- Stable to T° (>80°C) and pH (0-13)
- Highly resistant to CIP treatments

 Straightforward and regio-selective conjugation to resins, can be extended to other supports such as membranes

Ligand multimerization by genetic fusion

Affordable custom ligands

Simple and cost-effective animal free manufacturing by E. coli fermentation

 Scalability of NFs and resin production demonstrated at an industrial scale to insure a GMP compliant process

Development of tailor-made affinity chromatography columns



d=5cm

Case study of Gas25 vaccine purification

Actual process





Attributes	Standard process		NF process*
Purity RPC [%]	90		94
Integrity SEC [%]	84		91
Purity SDS- Page [%]	84		94
HCP-WB	Negative		Negative
DNA reduction [log]	2.5		4.8
DNA/protein ratio [ppm]	29		47
Bioburden (plates)	Negative		Negative
Process yield	38%		60%



- CIP conditions allow column regeneration (demonstrated beyond 35 cycles)
- No ligand leakage detected⁵
- Dynamic binding capacity: 15 mg/mL resin
- Clearance demonstrated for DNA, HCP, Bioburden, Endotoxins, IPTG
- Cost effectiveness compared to conventional process



1- Affilogic, Nantes, France 2- IBET, Oeiras, Portugal 3- Merck KGaA, Darmstadt, Germany 4- GSK Vaccines, Siena, Italy 5- below sensitivity of current methods



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And you, what would you purify with Affichrom' columns ?

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www.affichrom-separation.com