

**CERTIFICATE OF ANALYSIS nPROTEIN A, BULK**

Repligen Sweden AB article number: 11-1001

Batch number: \_ Manufactured (year-week): \_

Expire date (year-month): \_

Storage conditions:  $\leq -18^{\circ}\text{C}$

Product solution: 10 mM NaCl

Packaging: Sterile square bottle with screw closure (PETG/HDPE)

The batch is produced according to Manufacturing Formula, 21-1000 and according to Repligen Sweden AB Quality Policy, 01-1100.

<u>Test/Characteristic</u>	<u>Specification</u>	<u>Result</u>
Visual examination	n.r. = Clear yellowish or yellow-brown liquid	–
SDS-PAGE	n.r. = Comparable to reference	–
Purity by size exclusion chromatography	Min. 90.0 %	–
IgG-binding activity	Min. 95.0 %	–
Protein A concentration	$52.5 \pm 5.0$ mg/mL	–
Microbial contamination	Max. 5 CFU/mL	–
Content of enterotoxin B	Max. 1.0 $\mu\text{g/g}$ protein A	–
Endotoxin activity	Less than 50 EU/mL	–

n.r. = no remarks

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 Place and date

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 Name  
 QC, Repligen Sweden AB

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 Place and date

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 Name  
 QA, Repligen Sweden AB