

MACHEREY-NAGEL

Preparative scale isolation of vaccine-grade plasmid DNA

Bioanalysis



NucleoBond® RS – for high regulatory standards

Modular system for high-quality plasmid purification

- Endotoxin levels ≤ 0.01 EU/ μg DNA
- Closed columns for pump or FPLC processing
- Scalable system for up to 200 mg of plasmid DNA

MACHEREY-NAGEL

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NucleoBond® RS

Large-scale plasmid purification for processes with high regulatory standards

In response to rapid advancements in cell and gene therapy as well as vaccine production, the need for top-notch plasmid DNA has increased significantly. Emerging applications, such as mRNA-based vaccines and gene therapy treatments, rely heavily on superior plasmid DNA as a fundamental starting material. One of the most challenging aspects of these applications is dealing with endotoxins – components of cell walls from gram negative bacteria. Here's where MACHEREY-NAGEL's NucleoBond® RS comes into play. By employing the NucleoBond® RS workflow, you can achieve endotoxin levels ≤ 0.01 EU/ μ g DNA, ensuring compliance with stringent regulatory standards. NucleoBond® RS columns are designed for large-scale isolation of vaccine-grade plasmid DNA from bacterial cultures, utilizing peristaltic pumps or FPLC systems meeting the highest quality requirements.



Vaccine-grade
plasmid DNA!

Column Specifications

REF	Name	Theoretical binding capacity	ODV _{max}	Cell wet weight _{max}
743502	NucleoBond® RS 10	Up to 10 mg	3.000	8 g
743503	NucleoBond® RS 50	Up to 50 mg	15.000	40 g
743504	NucleoBond® RS 100	Up to 100 mg	30.000	80 g
743505	NucleoBond® RS 200	Up to 200 mg	54.000	145 g

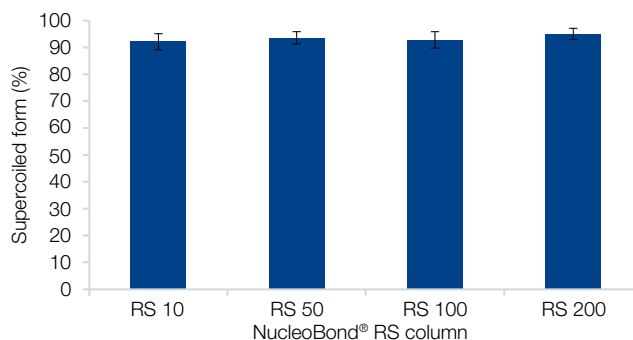
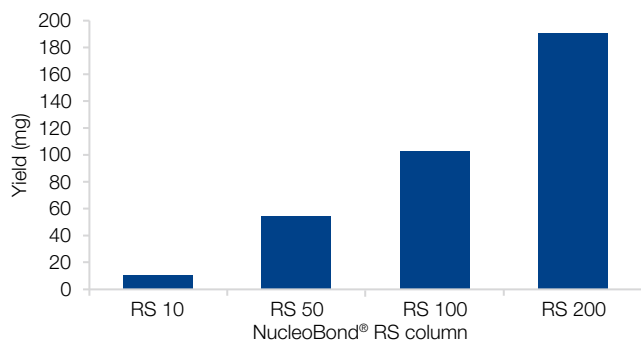


Plasmid DNA Specifications

Parameter	Method	Criterion
Integrity	AGE / Fragment Analyzer	≥ 90 % supercoiled form
Purity	UV spectrum	A_{260} / A_{280} 1.8 – 2.0 A_{260} / A_{230} 1.9 – 2.3
Endotoxin levels	LAL / rFC	≤ 0.01 EU/ μ g DNA
Host DNA	gPCR	≤ 1 %
Host RNA	AGE Fluorometric Quantification	Not visible at 200 ng DNA ≤ 2 %
Host Protein	BCA	≤ 1 %

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Application data – Large-scale plasmid DNA purification







The NucleoBond® RS purification workflow enables a straightforward scalability of your plasmid purification

Plasmid DNA was purified from *E.coli* with the four different sizes of our NucleoBond® RS columns. The figure shows the maximum amounts of plasmid DNA achieved per column size.

Plasmids isolated with NucleoBond® RS columns show very high structural integrity

The supercoiled form of plasmid DNA is considered to be the desirable form for applications like gene therapy or vaccination. Regulatory standards specify that plasmids have to be present with more than 90 % supercoiled form. These data show that plasmids isolated with our NucleoBond® RS columns meet these standards.

	 NucleoBond® RS 10	 NucleoBond® RS 50	 NucleoBond® RS 100	 NucleoBond® RS 200
Endotoxins (EU/µg DNA)	0.009 ± 0.004	0.007 ± 0.006	0.003 ± 0.002	0.003 ± 0.003
A_{260}/A_{280}	1.99 ± 0.04	1.97 ± 0.02	1.97 ± 0.04	1.98 ± 0.01
Supercoiled form (ccc) in %	92.3 ± 3.0	93.8 ± 2.1	93.0 ± 3.1	95.2 ± 2.1

Vaccine-grade plasmid DNA with more than 90 % supercoiled form

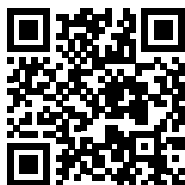
Technical data from plasmid isolations using our NucleoBond® RS columns show endotoxin levels ≤ 0.01 EU/µg DNA, A_{260}/A_{280} purity ratios between 1.8 – 2.0, and percentages of supercoiled (ccc) form ≥ 90 %.

NucleoBond® RS product features at a glance

- Vaccine-grade plasmid DNA with endotoxin levels ≤ 0.01 EU/µg DNA
- Scalable system for up to 200 mg
- Compatible with peristaltic pumps or FPLC systems, such as ÄKTA™
- Flexible component configuration
- High-quality plasmids as starting material for applications, like lentivirus/AAV production or IVT-RNA (e.g. mRNA)



Visit product website



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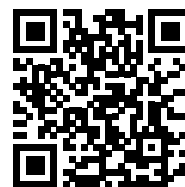
Easy scale-up
for your needs!

Compatible
with ÄKTA™
systems!

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Ordering information

To ensure maximum flexibility for our customers, we offer all components needed for plasmid purification with our NucleoBond® RS columns as standalone products. For more detailed information regarding equipment and quantities of individual components required per prep please check the user manual.



Scan
for user
manual!

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Name	Pack of / Volume	REF
NucleoBond® RS 10	5 columns	743502
NucleoBond® RS 50	1 column	743503
NucleoBond® RS 100	1 column	743504
NucleoBond® RS 200	1 column	743505
RES-EF	1000 mL / 3000 mL	740386.1000 / .3000
LYS-EF	1000 mL / 3000 mL	740387.1000 / .3000
NEU-EF	1000 mL / 3000 mL	740388.1000 / .3000
EQ-EF	1000 mL / 3000 mL	740380.1000 / .3000
ENTO-EF	1000 mL / 3000 mL	740381.1000 / .3000
WASH-EF	1000 mL / 3000 mL	740392.1000 / .3000
ELU-EF	900 mL / 3000 mL	740393.900 / .3000
TE-EF	1000 mL	740797.1
H ₂ O-EF (nuclease free)	1000 mL	740798.1
Liquid RNase A	2.5 mL	740397
RNase A (lyophilized)	100 mg	740505
NucleoBond® Bottle Top Filter Type 2	5 pieces	740553.5
NucleoVac 96 Vacuum Regulator	1 piece	740641
NucleoBond® Xtra Midi kit	10 preps	740410.10
NucleoSpin® Plasmid, Mini kit	50 preps	740588.50

Questions?

Contact the experts from MACHEREY-NAGEL technical support!

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System
EN ISO 13485:2016
ISO 9001:2015



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