

## Comparison of our quality grades: Minicircle

AVAILABLE IN  
**LARGE**  
SCALE!



	Research grade-MC	High Quality grade*-MC	GMP grade-MC
<b>Applications</b>	Optimized, highly efficient DNA for basic research, pre-clinical and toxicology studies	DNA starting material for early clinical phase GMP production of e.g., AAV, CAR-T cells or mRNA vaccines	DNA of highest quality as starting material for clinical phases and market supply or DNA for direct human application
<b>Characteristics</b>			
Guaranteed amount of minicircle DNA	☑	☑	(☑)**
Adjustment of DNA concentration included	☑	☑	☑
Customized filling included	☑	☑	(☑)**
Certified quality incl. QC report	☑	☑	☑
Storage of glycerol stock of parental plasmid and retain samples for repeat orders	☑	☑	☑
Antibiotics-free fermentation	☑	☑	☑
Cultivation media according to EMA/410/01 rev.3, 2011/C 73/01 (TSE/BSE certificate)	☑	☑	☑
All raw materials according to EMA/410/01 rev.3, 2011/C 73/01 (TSE/BSE certificate)	☑	☑	☑
Characterized and documented cell bank and pilot cultivation		☑	☑
Verified removal of bacterial endotoxins (LPS assay)	☑	☑	☑
Removal of RNA and proteins	☑	☑	☑
Specific removal of bacterial chromosomal DNA and oc-forms	☑	☑	☑
CGE analysis (ccc-supercoiled vs. oc plasmid topologies)	☑	☑	☑
Extended specification	(☑)**	☑	☑
Documentation acc. to GMP/GMP principles		☑	☑
Dedicated lab		☑	☑
QM system applied		☑	☑
Spatially separated upstream and downstream processes		☑	☑
Single use equipment			☑
Compliant with applicable GMP-guidelines and GMP certified			☑

\*HQ: High Quality Grade is produced in accordance with EMA guideline CHMP/BWP/2458/03 as the highest non-GMP quality standards | \*\*On request