

Quality Grades Overview

Characteristics	Scientific Quality (SQ) Grade		High Quality (HQ)* Grade	GMP Grade
	Research Grade	CCC Grade		
	Plasmid	Plasmid Minicircle	Plasmid Minicircle	Plasmid Minicircle
Produced by fermentation	✓	✓	✓	✓
Guaranteed amount of DNA	✓	✓	✓	✓
Adjustment of DNA concentration incl.	✓	✓	✓	✓
Customized filling included	✓	✓	✓	✓
Certified quality report incl.	✓	✓	✓	✓
Storage of glycerol stocks and retain samples for repeat orders	✓	✓	✓	✓
Antibiotic-free fermentation	✓	✓	✓	✓
Verified removal of bacterial endotoxins (LPS assay)	✓	✓	✓	✓
Removal of RNA and proteins	✓	✓	✓	✓
Removal of bacterial chromosomal DNA and oc-forms		✓	✓	✓
DNA in ccc-form (≥95% supercoiled)		✓	✓	✓
CGE analysis (ccc-supercoiled vs. oc-plasmid topologies)		✓	✓	✓
Extended specification		✓	✓	✓
Enzyme- and animal-free workflow		✓ ✗	✓ ✗	✓ ✗
Characterized and documented cell bank and pilot cultivation			✓	✓
Documentation according to GMP/GMP principles			✓	✓
Dedicated lab			✓	✓
QM system applied			✓	✓
Spatially separated upstream and downstream processes			✓	✓
Single use equipment for the entire process				✓
Compliant with applicable GMP-guidelines				✓

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

ccc: covalently closed circle CGE: Capillary Gel Electrophoresis

LPS: Lipopolysaccharide

oc: open circular