

GMP Plasmid DNA Vectors

Biomay Offers Innovative Contract Manufacturing Solutions for cGMP-grade DNA for Advanced Therapies



- pDNA as drug substance (API) for gene therapy or DNA vaccination
- pDNA as starting material for viral vector manufacturing (e.g. AAV)
- pDNA as vectors for cell therapy
- pDNA as template for mRNA transcription
- pDNA as template for siRNA or miRNA transcription



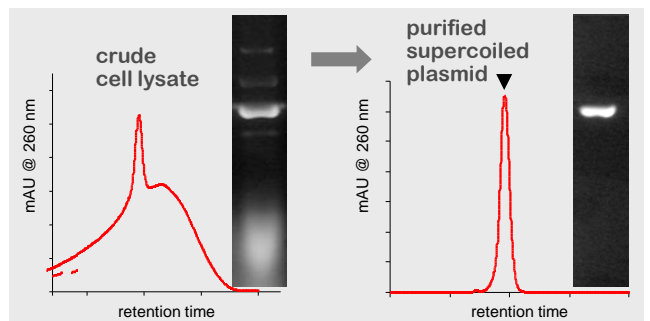
Producing Plasmids for Vaccination and Therapy

Biomay is a CMO for manufacturing of pharmaceutical plasmid DNA (pDNA). In this field, Biomay is specialized in the GMP-conform supply of highly pure pDNA for clinical phases I - III, with batch sizes ranging from 50 mg to 10 gram. Biomay's plasmid DNA manufacturing technology is completely large-scale compatible and comprises the following features:

- Robust, reliable and proven process design
- High-yield *E. coli* hosts
- High-cell density cultivation (25 L bioreactor)
- Optimized media (no antibiotics or animal compounds)
- Scalable alkaline lysis
- High-quality purification (up to 98 % supercoiled)
- Suitable for personalized (patient specific) batches

Quality and Specifications of pDNA

Parameters	Specifications Assay
DNA concentration	0.5 – 5 mg / mL HPLC / UV
DNA homogeneity	up to 98 % sc HPLC
DNA identity	100 % restriction / sequence
Endotoxins	≤ 1 EU / mg pDNA LAL test
Host cell protein	≤ 10 µg / mg BCA / ELISA
Host cell DNA	≤ 10 µg / mg qPCR
Host cell RNA	≤ 10 µg / mg agarose gel
Bioburden (sterility)	0 CFU / mL membrane filtr.



Biomay – a CMO with a Strong Plasmid Network

As a one-stop shop CMO, Biomay offers following services for therapeutic plasmid DNA:

- Vector design and cloning
- GMP cell banking
- Process and analytical development
- GMP manufacturing drug substance / start material
- GMP aseptic filling drug product (subcontracted)
- Tailored enzymatic processing & linearized vectors
- QP release and regulatory support
- ICH stability testing & long-term storage

Biomay's technology offers scalability, comparability, high yield and attractive pricing throughout the whole development chain.

In addition, a broad network of subcontractors widen Biomay's options of CMO services for pDNA.

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