

High Quality Grade Plasmid & Minicircle DNA

**Starting material for
GMP production of mRNA,
viral vectors & CAR-T cells**

Now in LARGE scale!

The better way to DNA!

Starting material for GMP production of mRNA, viral vectors and CAR-T cells in large quantities

The high-quality production of plasmid DNA as a starting material for the production of RNA vaccines has gained importance, especially in connection with the COVID-19 pandemic. As a promising vaccine candidate for the prevention of certain viral infections, RNA has the advantage of not integrating into the genome of the cell.

PlasmidFactory has developed and established the process for the production of the corresponding plasmid DNA. And we are now able to provide our products in large quantities!

How has the importance of plasmid DNA for pharmaceutical applications changed due to the increasing production of gene therapy vectors and COVID-19 mRNA agents?

Plasmids serve, for example, as starting material for the production of viral vectors (AAV, Lenti, etc.) and for the production of RNA. In particular, the production of plasmid DNA as a starting material for the production of RNA vaccines has become very important, especially in light of the COVID-19 pandemic situation, since RNA is considered a promising vaccine candidate for the prevention of certain viral infections and has the advantage of neither integrating into the genome of the cell nor remaining in the body of a patient as a potentially effective molecule in the long term.

parated from the purification (chromatography) to ensure that the downstream processing of the sensitive DNA is not affected by live contaminants. The proprietary special patented digestion and purification process results in a high level of pure, supercoiled (ccc) plasmid monomers that meet regulatory requirements to form a defined, homogeneous product that undergoes a series of cell bank and plasmid DNA product quality controls (QCs) prior to release. The corresponding QC report is then part of the delivered product, along with the release certificate.

What quality parameters do PlasmidFactory products offer?

In contrast to previously available processes, which were qualitatively and quantitatively sufficient for the production of plasmid DNA for research, a process must or had to be created now by which plasmids can be produced both in High Quality Grade HQ quality and in sufficient quantities. Due to the high quality requirements, this represents a considerable challenge, which currently has to be solved both in the area of fermentation and with regard to the chromatographic processing of the DNA product. Due to our expertise, especially in these areas, we see the PlasmidFactory in a pioneering role - we are happy to meet this challenge - so far very successfully!

What expertise and experience does PlasmidFactory have in producing plasmid DNA for pharmaceutical use?

With its now 20 years of experience in the field of DNA production, PlasmidFactory has an established process for the production of appropriate plasmid DNA, which meets the requirements to be used as starting material for the production of such RNA used in clinical applications: High Quality Grade Plasmid DNA. This high quality plasmid DNA is produced in a special facility: Starting from a characterized cell bank (RCB), the manufacturing process goes through several well-documented production steps. The HQ fermentation facility is spatially se-



PlasmidFactory's Products & Services

Customised plasmids and minicircles

PlasmidFactory's individual manufacturing service is frequently used by researchers from the fields of transfection and drug delivery, virus production, nanobiotechnology, gene therapy, cell or tumor therapy, and RNA or DNA vaccination. The company offers the production of plasmid and minicircle DNA in several quality grades: Research Grade and ccc Grade qualities for research purposes and pre-clinical applications, High Quality Grade as starting material for e.g. GMP production of RNA, viral vectors and CAR-T cells.

Minicircle – a safe vector system

Minicircles (MC) are circular DNA molecules that are generated e.g. by an intramolecular (cis-) recombination from a parental plasmid (PP). The difference between MC and standard plasmid vectors for gene therapy or nucleic acid vaccination is that the MC contains neither the bacterial origin of replication (needed only in bacteria for the amplification of plasmids in cell division) nor any antibiotic resistance markers or other selection systems to keep the plasmid in high amounts within the producer cell.

Hence, minicircles are the most promising tools to achieve both, increased efficacy as well as regulatory requirements for future clinical applications.

PlasmidFactory is the exclusive owner of all relevant patents and IP in this field and provides service production of these supercoiled monomeric constructs, according to clients' requirements.

In Stock Services

Our In Stock products are deliverable immediately "off-the-shelf" – e.g. reporter genes (gfp, lacZ, luc), AAV Helper & Packaging plasmids (pDG/pDP family, several serotypes) or pEPI plasmids (containing S/MAR elements).

Other services

On request, plasmid DNA storage and logistics can be organized, supplementing the company's service portfolio.

PlasmidFactory's proprietary method for quantification of the structural diversity of plasmid DNA by means of capillary gel electrophoresis (CGE) is the only reliable method able to determine the stability of plasmid DNA during storage.



PlasmidFactory is the leading contract manufacturer of plasmid and minicircle DNA and the driving force in the development of gene vectors for gene and cell therapy and genetic vaccination.

PlasmidFactory's complete services as well as research and development are located in Bielefeld, Germany.



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Number of Employees

Founded

31

2000

Biological Patents

PlasmidFactory owns any relevant know-how, patents and licenses for plasmid and minicircle manufacturing

External Collaborations

Fruitful long-term cooperations with renowned academic and industrial institutions in the fields of gene and cell therapy and vaccination

Areas of activity

- Contract Manufacturing of plasmid and minicircle DNA in different quality grades for research up to clinical applications
- High Quality Grade plasmid and minicircle DNA as starting material for GMP productions, e.g. of mRNA, viral vectors and CAR-T cells, also in gram scales
- In Stock Service for AAV Helper & Packaging Plasmids (pDG/pDP) and for further plasmids and minicircles (e.g. reporter genes)
- Analysis of plasmid topology

PlasmidFactory.com