1. Product Information

Product name	**pBM-LV-GagPol**
Catalog Nr.	522-01-GMP (1 mg) / 522-05-GMP (5 mg) / 522-10-GMP (10 mg)
Quality grade	Good Manufacturing Practice (GMP)
Description	DNA plasmid encoding the HIV-1 *gag* and *pol* genes, intended for preparation of lentiviral particles
Plasmid Size	7 787 bp
Molecular weight	4 830 kDa
Concentration	1.0 ± 0.2 mg/mL solution in buffer (frozen)
Storage buffer	10 mM Tris-HCl, 1 mM EDTA, pH 8.0 (TE buffer)
Storage temperature	-20 ± 5 °C
Lot. Nr.	Specified on product label
Use by date	Specified on product label
Manufacturer	Biomay AG, Ada-Lovelace-Straße 2; 1220 Vienna, Austria; www.biomay.com; info@biomay.com

2. Description

Lentiviral packaging plasmid encoding the HIV-1 *gag* and *pol* genes (NCBI Reference: K03455.1) under control of the CMV promoter (NCBI Reference: GU937742.2). The plasmid can be used in 3rd generation lentiviral systems. The plasmid was propagated by cultivation in *Escherichia coli*, purified by chromatographic methods, 0.2 µm filtered and filled as low bioburden product. Sequence information as .gb or .fasta-file can be provided upon request.

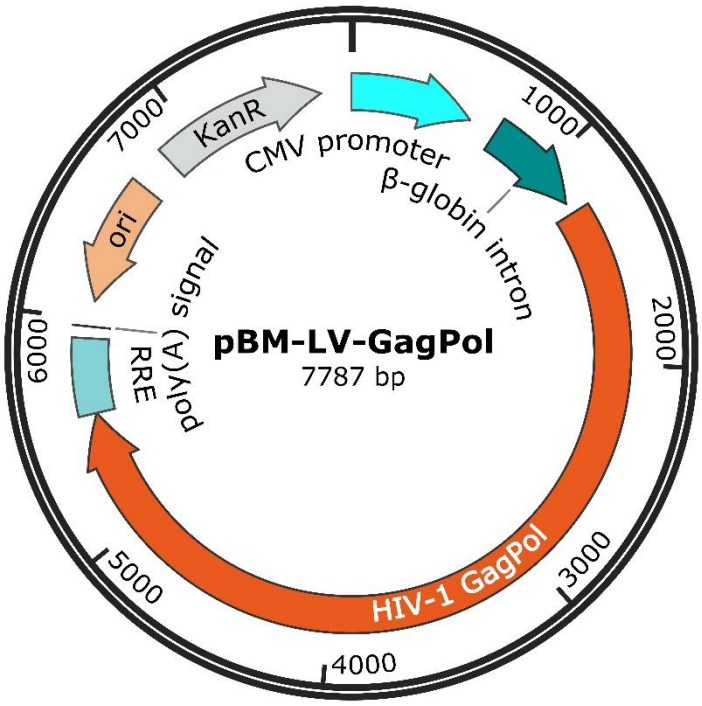
3. Intended Use / Application

GMP grade: product is a DNA plasmid that has been manufactured and quality-controlled under the conditions of Good Manufacturing Practice (GMP). It has been certified and released by a Qualified Person (QP) under EMA law (EMA directive 2001/83/EC). It was designed and is intended to be used in conjunction with a lentiviral (LV) envelope plasmid, one or more lentiviral (LV) packaging plasmid(s) and a lentiviral (LV) transgene plasmid to transfect HEK293 cells, in order to manufacture lentiviral vector (LV) particles. The quality of this product is considered appropriate to serve as a starting plasmid for the GMP manufacturing of clinical-grade LV virus particles which may be used as gene transfer vector for human clinical trials.

4. Safety information

Material is considered non-infectious, non-toxic and non-pathogenic under the conditions of the intended applications. General safety procedures should still be followed to maintain a safe working environment. Always wear appropriate personal protective equipment (PPE), including lab coats, gloves, and safety glasses, to avoid contamination and accidental exposure. Work in a clean, organized space, and handle reagents with care, avoiding direct contact. Dispose of all waste materials, including gloves and pipette tips, in designated biohazard containers, even though the plasmid DNA is non-hazardous, to prevent cross-contamination. Always wash hands after handling any biological material and before leaving the lab.

5. Plasmid Map



6. Testing Specifications

Parameter	Method	Specification *GMP-grade*
Appearance	Visual inspection	Clear and colourless solution; free from visible particulates
pH value	pH measurement	8.0 ± 0.5
pDNA homogeneity (% supercoiled)	Anion exchange HPLC	> 85 % supercoiled
DNA concentration	UV spectrophotometry (A_{260})	1.0 ± 0.2 mg / mL
Purity based on A_{260}/A_{280} ratio	UV spectrophotometry (ratio A_{260}/A_{280})	1.8 – 2.1
Identity / Integrity	Restriction digest & agarose gel electrophoresis	Major bands conform to theoretical fragments (expected band pattern)
pDNA sequence	DNA sequencing (complete sequence)	Conforms to reference sequence
Residual host cell DNA	qPCR	< 1.0 % (< 10 µg / mg DNA)
Residual host cell RNA	Fluorometry	< 2.0 % (< 20 µg / mg DNA)
Residual host cell protein	Colorimetry	< 1.0 % (< 10 µg / mg DNA)
Endotoxin	Kinetic chromogenic LAL test (Ph. Eur. 2.6.14 / USP <85>)	≤ 5.0 EU / mg DNA
Bioburden	Testing for bacteria, yeasts & moulds (Ph.Eur.2.6.12/USP <61>)	< 1 cfu / mL