1. Product Information

Product name	**pBMY-AAV2**
Catalog Nr.	502-01-GMP / 502-05-GMP / 502-10-GMP
Quality grade	Good Manufacturing Practice (GMP)
Description	DNA plasmid encoding Rep2/Cap2 genes of adeno-associated virus (AAV), intended for preparation of AAV particles of serotype 2
Plasmid Size	6 104 bp
Molecular weight	3 772 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

AAV Rep/Cap plasmid encoding p5 promoter and Rep/Cap genes of AAV serotype 2 (NCBI Reference: NC_001401.2). 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

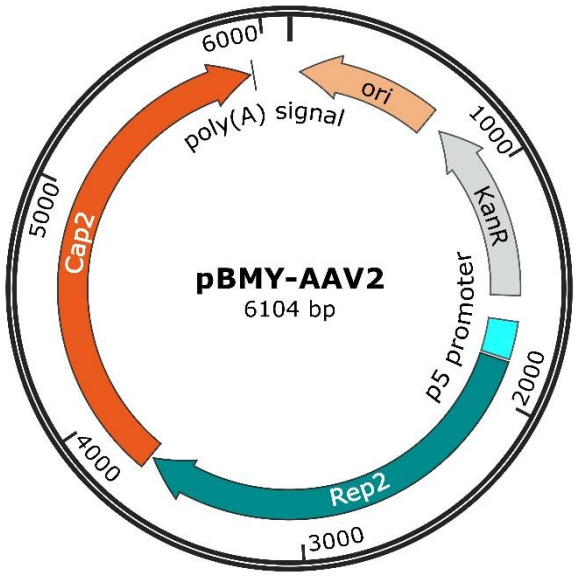
GMP grade: product is a DNA plasmid that has been manufactured and quality-controlled under the conditions of Good Manufacturing Practice (GMP). It has been certified and released by a Qualified Person (QP) under EMA law (EMA directive 2001/83/EC).
It was designed and is intended to be used in conjunction with an adenoviral (Ad) helper plasmid and an AAV transgene plasmid to transfect HEK293 cells, in order to manufacture adeno-associated virus (AAV) particles.

The quality of this product is considered appropriate to serve as a starting plasmid for the GMP manufacturing of clinical-grade AAV 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