

DATA SHEET

Plasmid Manufacturing Services

KromaTiD's Plasmid Manufacturing Service offers plasmid DNA in a range of purity levels and amounts with fast turnaround and competitive pricing.

Our team can provide the best plasmid manufacturing service for any stage along the development pipeline, from research to IND filing to commercial manufacturing.

Key Benefits

- Three levels of purity: Research, Transfection and Low Endotoxin Grades
- Three production modes: research, pre-GMP and cGMP
- Compatible with your materials; simply provide pDNA as frozen glycerol stock or stabs for cultures.
- Choose the amount of DNA you need, from 100μg to 5g scales.
- Fast turnaround and highly competitive pricing
- Standard documentation and QC provided.
- Additional tests provided on request.

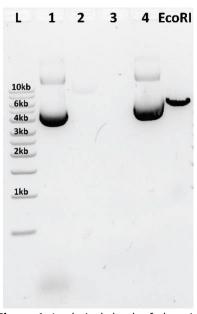
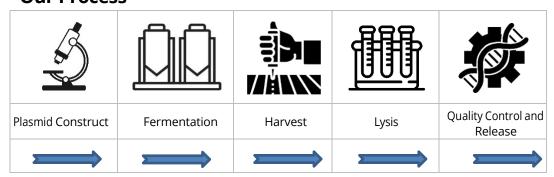


Figure 1. Analytical check of plasmid purification, pAAV-GFP. L: ladder, 1: cleared lysate, 2: lysate flow-through, 3: wash flow-through, 4: eluate, EcoRI: enzymatic digestion.

Our Process







Purity Levels

Plasmid DNA Grades	Scale	Application	Production
Research Grade	100ug-2.5mg	<i>In vitro</i> R&D or preclinical studies	R&D Grade for cloning or vector construction
Transfection Grade	100ug-1g	<i>In vitro</i> R&D or preclinical studies	Transfection Grade for less sensitive cells
Low Endotoxin Grade	100ug-1g	<i>In vitro</i> R&D or preclinical studies	Low Endotoxin Grade for sensitive cells
High Quality Pre-GMP	<u>></u> 50mg	Toxicology, GMP vector production for Phase I- II clinical trials, and as template for GMP mRNA	Dedicated, segregated Non-cGMP Lab (~6 weeks to supply)
cGMP	<u>></u> 50mg	Phase I, II, III and commercial viral vector manufacturing, DNA vaccines	Certifiable suite for GMP manufacturing (inquire for availability)





Plasmid Manufacturing Production Mode Comparison

Service Provided	Research	Pre-GMP	cGMP
Cloning and Synthesis	✓	✓	✓
Multiple production scales (shake flask through fermenters)	✓	✓	\
Proven manufacturing and purification processes for high yield and recovery	✓	✓	✓
Standardized manufacturing platforms	✓	✓	✓
Establishment and maintenance of working cell bank	✓	✓	✓
Upstream process development (optimization of transformation and culture conditions, strain, etc.)	✓	✓	√
Downstream process development (optimization of purification and formulation conditions)	✓	✓	✓
Product release tests	✓	✓	✓
Production in segregated and dedicated space		✓	✓
Document support for IND filing		✓	✓
Master Batch Records		✓	✓
Manufacturing in cGMP suite with upgraded air handling			✓
Complete QC monitoring throughout production process			✓
QA Oversight for production			✓

Quality Control

QC Items	Specification	Measurement Method	Research	Pre-GMP	cGMP
A260/280	1.8–-2.0	Nanodrop UV Absorption	Standard	Standard	Standard
Appearance	Clear	Visual Inspection	Standard	Standard	Standard
Concentration	On request, standard is 0.25 mg/ml	Nanodrop UV Absorption	Standard	Standard	Standard
Restriction Digest	Matches reference	Gel Digest	Standard	Standard	Standard
Genomic DNA	Not Visible	Gel Digest, qPCR	Request	Standard	Standard
Residual RNA	Not Visible	Gel Digest	Request	Standard	Standard
Endotoxin Assay	< 0.1 EU/ug plasmid DNA	LAL Assay	Request	Standard	Standard
Sequencing	Matches reference	NGS	Request	Standard	Standard
ITR Integrity	No replication errors	Gel Digest, NGS	Request	As needed	As needed
BioBurden Assay	No growth	Agar plate for 48 hours	Request	Request	Standard
Mycoplasma	No Mycoplasma content	PCR	Request	Request	Request





Pricing and Turn Around Times

Cat.No.	Product Description	TAT	List Price
KPM-001	Research-Grade up to 100ug yield	5-10 days	\$437.50
KPM-002	Research-Grade up to 200ug yield	5-10 days	\$443.10
KPM-003	Research-Grade up to 500ug yield	5-10 days	\$448.35
KPM-004	Research-Grade up to 1mg yield	5-10 days	\$458.85
KPM-005	Research-Grade up to 2.5mg yield	5-10 days	\$511.70
KPM-006	Research-Grade >2.5mg yield	Inquire	Inquire
KPM-007	Transfection-Grade up to 100ug yield	5-10 days	\$439.43
KPM-008	Transfection-Grade up to 200ug yield	5-10 days	\$457.10
KPM-009	Transfection-Grade up to 500ug yield	5-10 days	\$461.48
KPM-010	Transfection-Grade up to 1mg yield	5-10 days	\$669.10
KPM-011	Transfection-Grade up to 2.5mg yield	5-10 days	\$802.55
KPM-012	Transfection-Grade >2.5mg yield	Inquire	Inquire
KPM-013	Low Endotoxin-Grade up to 100ug yield	5-10 days	\$449.50
KPM-014	Low Endotoxin-Grade up to 200ug yield	5-10 days	\$467.25
KPM-015	Low Endotoxin-Grade up to 500ug yield	5-10 days	\$474.25
KPM-016	Low Endotoxin-Grade up to 1mg yield	5-10 days	\$735.00
KPM-017	Low Endotoxin-Grade up to 2.5mg yield	5-10 days	\$861.00
KPM-018	Low Endotoxin-Grade >2.5mg yield	Inquire	Inquire
KPM-019	Pre-GMP Grade up to 50mg yield	-6 weeks	Inquire
KPM-020	cGMP Grade 100mg to 5g yield	Inquire	Inquire
KPM-021	DNA Synthesis per DNA basepair	4-8 weeks	Inquire
KPM-022	Sanger Sequencing Verification	5 days	Inquire
KPM-023	NGS Sequencing Verification	5 days	\$170.00