

MYCENAX

PLASMID DNA MANUFACTURING



PlasMX™ One-stop CDMO SOLUTION



Fast Turnaround Time

Research-grade plasmids can be provided within 2 weeks.



High Quality

≥90% supercoiled plasmids with low endotoxin and host impurities.



Flexible Solution

Meet your requirements for research, high-quality, and GMP grades.

PLASMID DNA PRODUCTION

Mycenax's plasmid platform **PlasMX™** prioritizes both speed and quality, delivering plasmid DNA in various grades and amounts to meet your specific requirements.

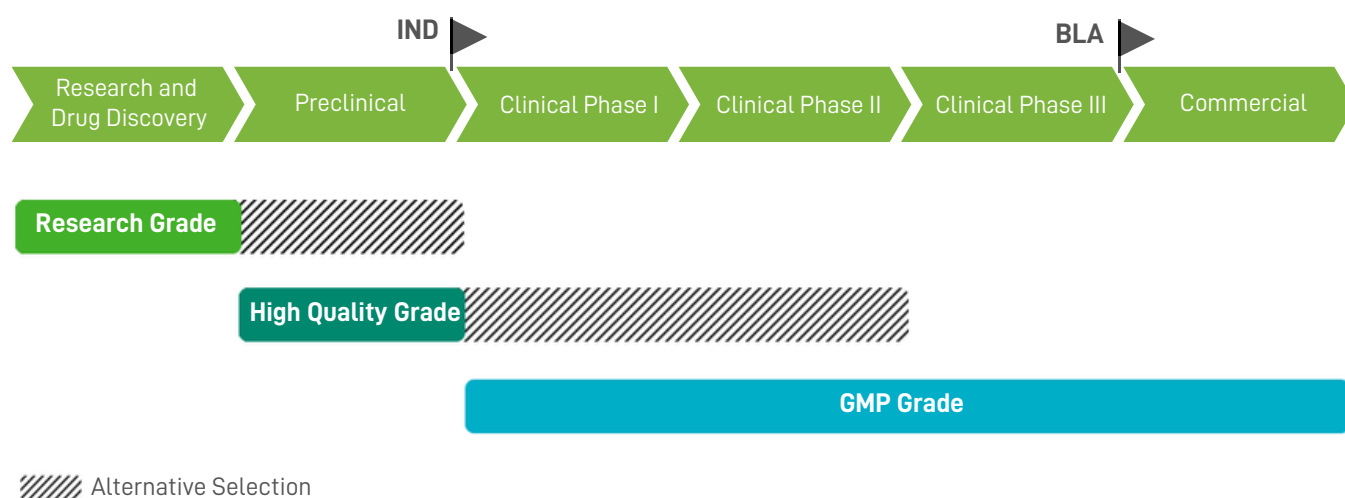
With manufacturing capabilities ranging from 5L to 200L scale, we support applications from research to commercialization.

PLASMID DNA APPLICATION

- Viral vector production
- Cell and gene therapy
- DNA vaccines
- mRNA production

PHASE-DEPENDENT APPROACHES

Mycenax offers three different grades of plasmids, each designed to fulfill the specific requirements of various applications.



Description	Research Grade	HQ Grade	GMP Grade
Application	<ul style="list-style-type: none"> • Research and drug discovery • Preclinical studies 	<ul style="list-style-type: none"> • Preclinical studies • Clinical phase I/II trials 	<ul style="list-style-type: none"> • Clinical trials • Commercialization
Turnaround Time	2W+	3W+	8W+
Production Area	<ul style="list-style-type: none"> • PD laboratory 	<ul style="list-style-type: none"> • PD laboratory • Classified GMP production suite 	<ul style="list-style-type: none"> • Classified GMP production suite
Critical Quality Attributes Testing	✓	✓	✓
Certificate of Analysis (CoA)	✓	✓	✓
Dedicated Critical Materials		✓	✓
TSE/BSE Statement		✓	✓
Manufacturing Batch Record			✓
Environmental Monitoring			✓
Validated QA Oversight			✓

PROCESS WORKFLOW



QUALITY CONTROL

Test Item	Method	Specification	Research Grade	HQ Grade	GMP Grade
Appearance	Visual Inspection	Clear, no visual particles	V	V	V
Concentration	UV Spectrophotometry	Product Specific	V	V	V
pH	USP<791>	Product Specific	V	V	V
Purity	UV Spectrophotometry (A_{260}/A_{280})	1.8-2.0	V	V	V
DNA Homogeneity (Supercoiled Content)	Gel Electrophoresis	≥80%	V	-	-
	HPLC	≥80%	Δ	-	-
	HPLC	≥90%	-	V	V
Plasmid Identity	Gel Electrophoresis	Conform to reference	V	V	V
Restriction mapping	Gel Electrophoresis	Conform to reference	V	V	V
DNA Sequence	Sanger Sequencing	100% identical to expected sequence	V	V	V
Residual Host Cell Protein	Micro BCA	≤5%	V	-	-
	ELISA	≤5%	Δ	-	-
	ELISA	≤2%	-	V	V
Residual Host Genomic DNA	Gel Electrophoresis	Not visible	V	-	-
	qPCR	≤5%	Δ	-	-
	qPCR	≤2%	-	V	V
Residual Host RNA	RiboGreen	≤5%	V	-	-
	RiboGreen	≤2%	-	V	V
Endotoxin	USP<85> Kinetic Chromogenic Method	≤100 EU/mg	V	-	-
	USP<85> Kinetic Chromogenic Method	≤10 EU/mg	-	V	V
Residual Kanamycin	ELISA	As reported	-	Δ	V
Bioburden	USP<61> Microbial Enumeration	As reported	-	Δ	-
	USP<61> Microbial Enumeration	TAMC: ≤ 10 CFU/10 mL TYMC: ≤ 10 CFU/10 mL	-	-	V

V: Default Δ: Optional -: Not applicable

PlasMX™ One-stop CDMO SOLUTION

2+

Week Turnaround Time

≥90%

Product Purity

3

Quality Grades

