

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.

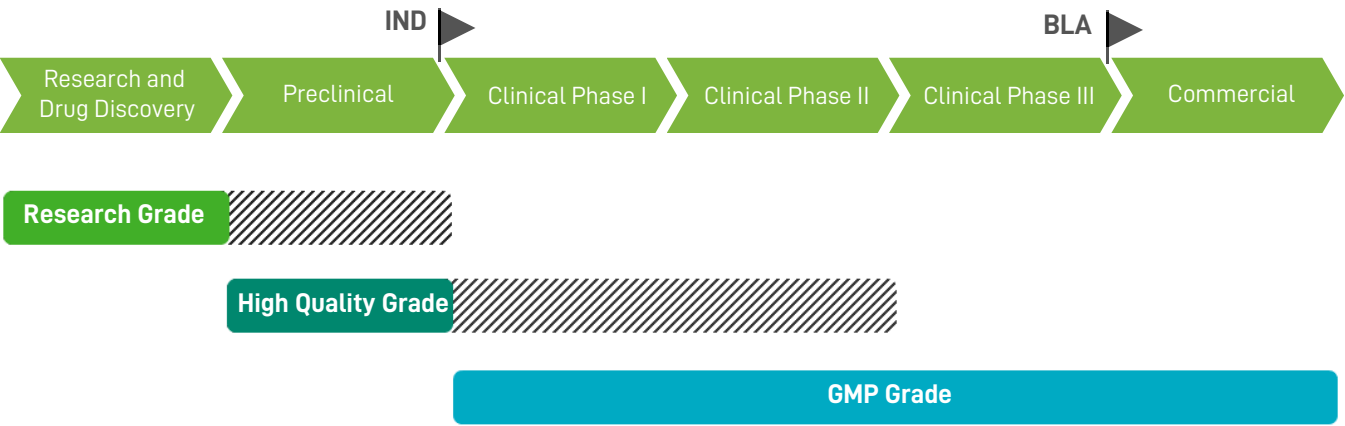
With manufacturing capabilities ranging from 5L to 200L scale, we support applications from research to commercialization.

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.



Alternative Selection

| 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% | △ | - | - |
| | 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% | △ | - | - |
| | ELISA | ≤2% | - | V | V |
| Residual Host Genomic DNA | Gel Electrophoresis | Not visible | V | - | - |
| | qPCR | ≤5% | △ | - | - |
| | 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 | - | △ | V |
| Bioburden | USP<61> Microbial Enumeration | As reported | - | △ | - |
| | USP<61> Microbial Enumeration | TAMC: ≤ 10 CFU/10 mL TYMC: ≤ 10 CFU/10 mL | - | - | V |

V: Default △: Optional - : Not applicable

PlasMX™ One-stop CDMO SOLUTION

2+

Week Turnaround Time

≥90%

Product Purity

3

Quality Grades

