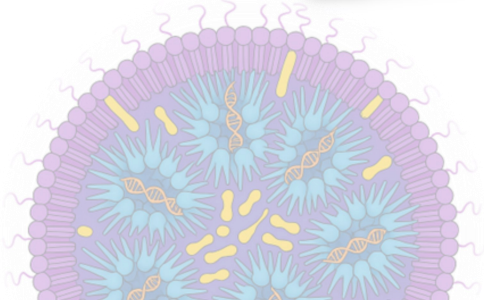
PreciGenome

NanoGenerator® MAX cGMP System

Advanced Microfluidic Technology for Clinical and Commercial Nanoparticle Production



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NanoGenerator® Max Nanoparticle Synthesis System

The NanoGenerator® platform ensures consistent critical quality attributes (CQAs) throughout the entire development and manufacturing process. With PreciGenome's microfluidic technology, customers can seamlessly transfer early discovery results (NanoGenerator® Flex to the late stage production (NanoGenerator® Max).

The NanoGenerator® Max RUO version can be used for preclinical applications of LNP synthesis, while the NanoGenerator® Max GMP version is designed for clinical and commercial production.

System Benefits

High Performance & Efficiency

- Tunable size (40-200nm)
- Low PDI
- High encapsulation efficiency

Regulatory Compliant

- Intuitive software (21 CFR Part 11 compliant)
- Single-use flow kit
- Certificates & reports

Scalable & Reproducible

- Scale-up and minimum process development
- Direct transfer from clinical development to commercial manufacturing
- Reproducible manufacturing

Automation & QC

- Automated workflow
- Real-time flow rate monitoring & recording
- Electronic batch records

Cost Effective

- Affordable system
- Low cost consumables

Custom Design & Service

- On-site 3Q installation & qualification
- Custom design & OEM

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Address: 2176 Ringwood Ave., San Jose, CA, USA
Visit us at www.precigenome.com/nanoparticle-synthesis

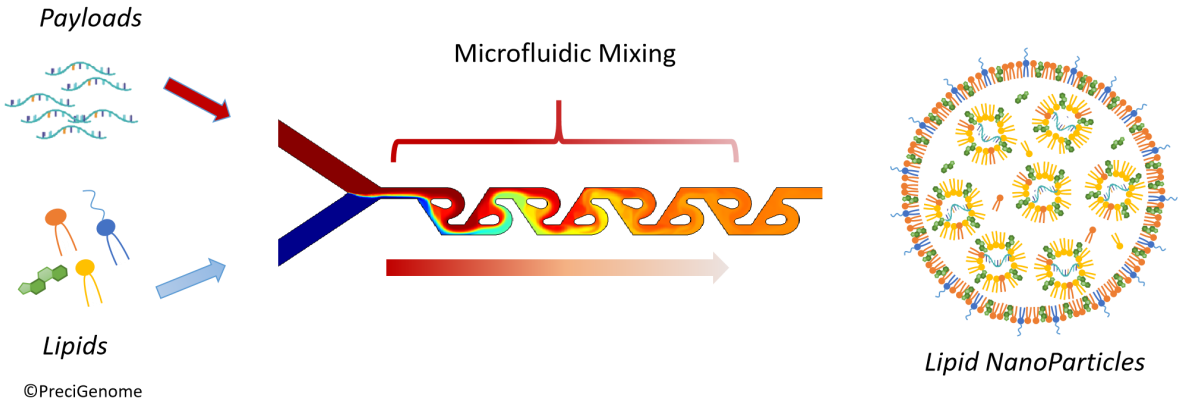
Advanced Microfluidic and Flow Control Technology

Nanoparticle synthesis via microfluidic mixing has superior control of size, homogeneity, and repeatability to conventional batch synthesis methods. Two streams, aqueous and solvent, meet in a narrow mixing channel, forming nanoparticles with payload encapsulated.

PreciGenome's NanoGenerator® platform uses pressure-based microfluidics for reliable nanoparticle synthesis at several production scales. It has been widely used to produce various types of nanoparticles, such as lipid nanoparticles (LNPs), liposomes, PLGA nanoparticles, etc.

Microfluidic Mixing System

- Controllable particle size
- Low PDI
- High encapsulation efficiency
- High reproducibility



System Applications

Nucleic Acid Lipid Nanoparticles

- mRNA vaccines
- Rare genetic diseases
- Gene & cell therapy
- CAR-T therapeutics

Liposomes

- Cancer therapy
- Vaccine adjuvant
- Antimicrobial therapy
- Cosmetics

Polymer Nanoparticles

- Cancer chemotherapy
- Immunology & vaccines
- Insulin delivery for diabetes

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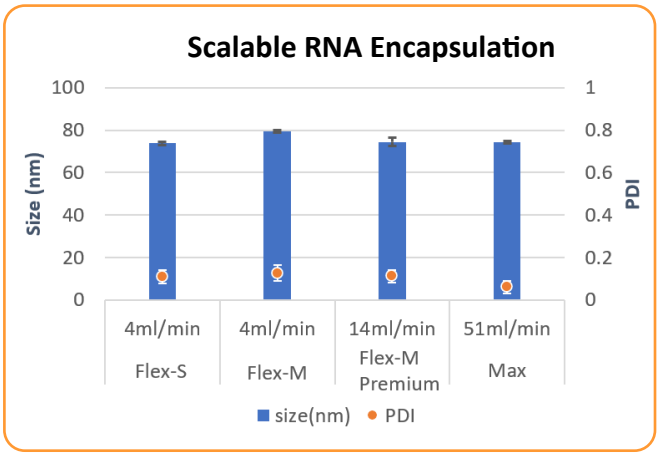
NanoGenerator® Max Lite & Max cGMP Nanoparticle Synthesis System

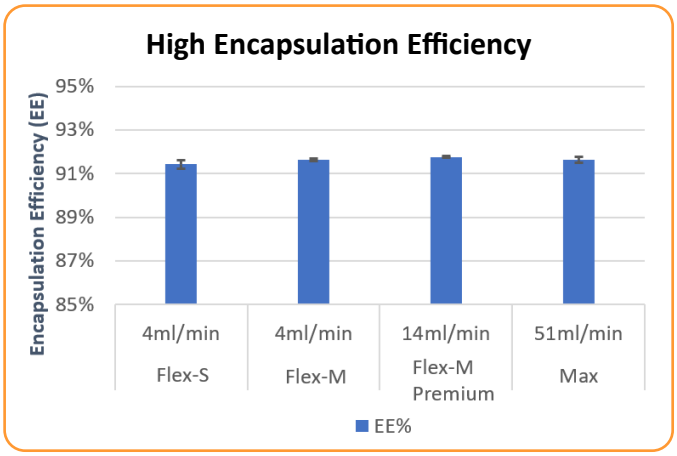
With PreciGenome's microfluidic technology, customers can seamlessly transfer early discovery results (NanoGenerator® Flex) to the late stage production (NanoGenerator® Max Lite & Max).

The NanoGenerator® Max RUO version can be used for preclinical applications of LNP synthesis, while the NanoGenerator® Max Lite & Max GMP version is designed for clinical and commercial production.

NanoGenerator® Max Lite

NanoGenerator® Max





Model	NanoGenerator® MAX Lite	NanoGenerator® MAX			
		RUO flow kit	GMP flow kit	RUO flow kit	GMP flow kit
cGMP compliance	Yes	N/A	Yes	N/A	Yes
Software (21 CFR Part 11)	Yes	Optional	Yes	Optional	Yes
Throughput	5 – 200 ml	50 ml – 1 L		> 20 L (continuous production)	
Max flow rate	24 ml/min	4.8 L/h		40 L/h	
Flow rate ratio	1:1 – 9:1	1:1 – 9:1		1:1 – 5:1	
Inline dilution	1:1 – 5:1				
Size range & PDI	40 – 200 nm (size), 0.05 – 0.2 (PDI)				
Encapsulation efficiency	Up to 99%				
Dimension (L × W × H)	420 × 300 × 300 mm	620 × 380 × 430 mm			
Weight	35 kg	50 kg		65kg	

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Regulatory Compliance

The NanoGenerator® MAX GMP System is engineered to facilitate the production of genomic medicines for both clinical and commercial purposes.

Regulatory support files for the single-use mixing flow pack are available including material traceability documentation .

PreciGenome has a proven history of delivering timely support to assist our customers in fulfilling their unique country- or region-specific regulatory requirements. The GMP System is manufactured under a Quality Management System.

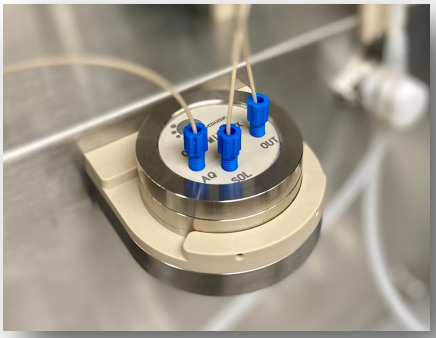
cGMP Compliance Documentation

- Installation qualification, operational qualification, performance qualification
- Report of consumable extractables test
- Report of endotoxin test
- Report of RNase/DNase free test
- Report of sterility test
- Report of ethylene oxide residual test
- Report of consumable air tightness test
- Electromagnetic compatibility report
- Safety regulations report

Single-use mixing flow pack

The single-use mixing flow pack is fully documented to support regulatory and quality audits for cGMP production.

It reduces the risk of cross-contamination between batches and campaigns. It also enables multi-product manufacturing in GMP



Software (21 CFR Part 11 compliant) features

- Experimental parameter tuning
- Experimental recipe save/load
- Real-time pressure/flow rate chart
- Historic experimental parameter tracking
- Historic pressure/flow rate tracking
- Self-diagnostic system
- Real-time flow rate diagnostic system
- Warning system
- Manual & automatic emergency stop system
- User management
- Audit trail
- Zero flow calibration
- Flow sensor maintenance & re-calibration (service)

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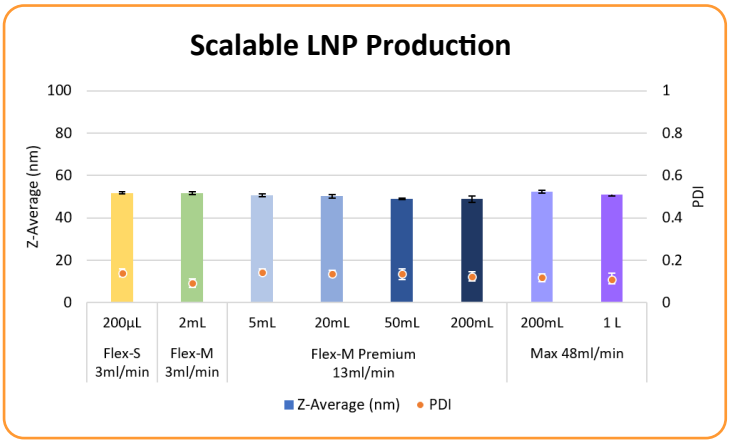
Path from Discovery to Commercialization

NanoGenerator® offers controllable and reproducible mixing conditions, ensuring the accurate synthesis of LNPs through its scalable architecture found in the entire NanoGenerator® product line. Options are available for all production stages, allowing seamless transfer of crucial process parameters and guaranteeing consistent critical quality attributes (CQAs). LNPs produced from NanoGenerator® may be used for a wide range of applications, such as vaccine development, gene therapy, cell therapy, etc.



Discovery & Screening | Pre-Clinical | Clinical | Commercial

Flex-S
- 0.1 - 2mL per run
- 1 - 4 samples per run

Flex-M
- 1 - 12mL per run

Flex-M Premium
- 1 - 200 mL per run

MAX Lite cGMP
- 2 - 200mL per run

Flex-S Plus
- 0.1 - 0.5mL per sample
- 48 samples per run
- 96 samples within 90 mins

MAX (RUO)
- 50mL - 1L per run

MAX cGMP (4.8L/h)
- 50mL - 1L per run

MAX cGMP (40L/h)
- Continuous production

Custom design and OEM solutions

Target Validation
API Identification
Excipient Identification

Formulation Development
& Optimization
Candidate Selection

Clinical Development
Approved Medicine
Customized GMP Solution

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PreciGenome is located in the heart of Silicon Valley, San Jose, California, USA. We have been focusing on developing nanoparticle synthesis systems and solutions for our customers. Our technology enables nanoparticle synthesis with high quality and reliable performance for lipid nanoparticles, liposomes, PLGA, etc.

HEADQUARTER

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Some of Our NanoGenerator Customers

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