Micropore Technologies

AXF™ Pathfinder

Integrated Design of Experiment (DOE) device

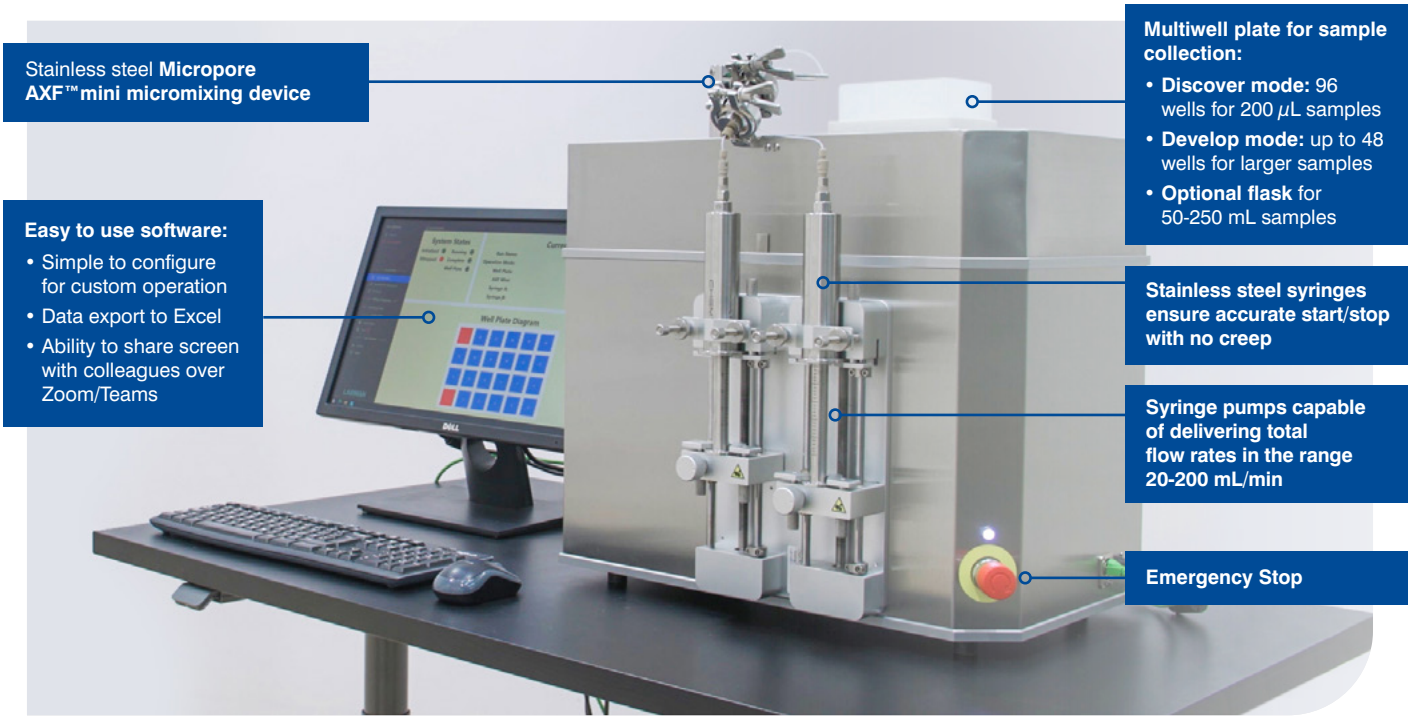
The AXF™ Pathfinder for Discovery, Development, Preclinical & 21 CFR Part 11 development of RNA/LNP therapeutics and vaccines.

Harnessing the capabilities of Micropore's award-winning AXF™mini, together with intuitive software, the AXF™Pathfinder is a compact benchtop unit for Discovery, Development and Phase I Clinical Development of nucleic acid therapeutics and vaccines.

The high throughput AXF™ Pathfinder rapidly generates samples into either a standard multi-well plate or conical flask enabling more efficient preclinical and clinical development for new more easily scalable nucleic acid therapies.

In addition to high throughput screening, the AXF™ Pathfinder accelerates development by eliminating tech transfer iterations during scale up, transitioning from DOE screening to clinical production on a single device.

- A single device from initial discovery into the clinic: 200 µL to 250 mL sample volumes
- Simple to set up and operate
- No consumables and extremely low maintenance
- 200 µL sample size in DISCOVER mode for development and in vitro analysis
- User determined sample size in DEVELOP mode for immediate scale up for in vitro and in vivo studies
- Minimal waste
- GMP ready
- Customisable with a range of options



Simple to set up and operate

Set up and operation of the Pathfinder is straightforward requiring minimal training with users able to set their own operating parameters or use operating pre-sets including an automated cleaning cycle. Intuitive control software via a connected PC enables real time onscreen sharing of data. A key feature of the AXF™ Pathfinder is the lower operating cost as there are no consumables or costly maintenance requirements.

DISCOVER mode

DISCOVER mode enables initial formulation with minimised wastage for development and analysis. The AXF™ mini's extremely low internal volume means that start-up waste for the Pathfinder unit is only around 400 µL and sample sizes can be as small as 200 µL.

High throughput screening of up to 96 samples in less than a minute for rapid DOE and process optimisation.

DEVELOP mode

DEVELOP mode with sample sizes of up to 20 mL enables straight-forward scale up, in depth characterisation, and in vitro or in vivo testing.

Control independent of formulation

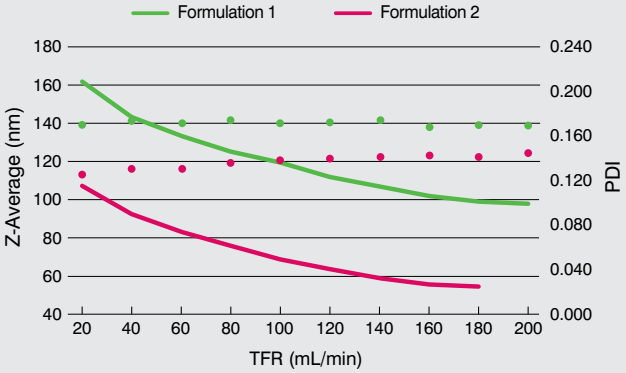


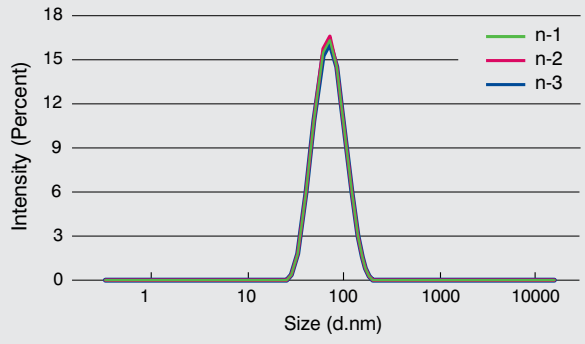
Illustration of particle size tunability with PolyA loaded LNPs:

Z-Average decreases with increasing flow rate while Pdi remains well below 0.2.

Different formulations exhibit similar Z-Average curves even though each formulation has different fundamental size characteristics.

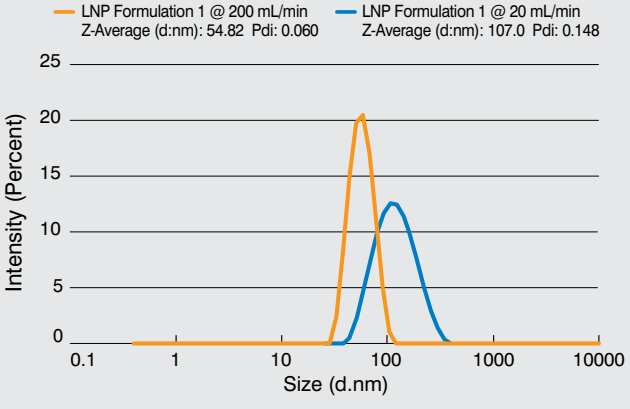
These curves allow predictable control over size in a manufacturing environment and lend themselves well to operation under PAT.

LNP formulation repeatability: n=3 at 100 mL/min



	Z-Average (d.nm)	Pdi
Average of n = 3	**68.68**	**0.131**
Standard deviation	**0.31**	**0.003**

Total flow rate controls LNP size



Same formulation results at different flow rates.

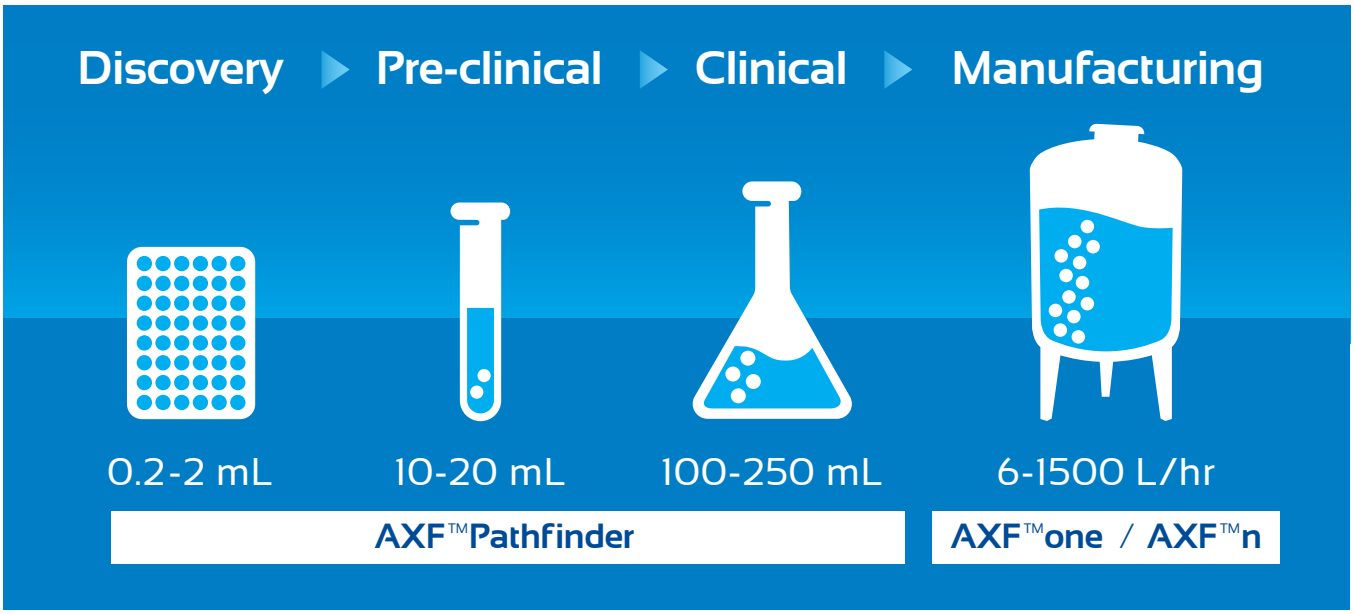
GMP ready

The Pathfinder is constructed from medical grade stainless steel, under a ISO9001 Quality Management System. It is a GMP compliant product with no consumables other than replacement PTFE O-rings.

Configuration versatility

There are a number of options which extend the capability of the AXF™ Pathfinder

- Multiple samples collected in rack of 50 mL tubes
- Single sample of up to 250 mL
- Inline dilution to increase LNP stability
- 21 CFR part 11 compliance



Establish the protocols then just increase the volume

Commencing development with Micropore's AXF™ micro-mixing de-risks development from the outset.

The flexibility of the AXF™ Pathfinder enables development from the first very small sample suitable for in vitro analysis, through larger samples for in vivo analysis and animal studies, up to 250 mL for early clinical material.

The consistency of our AXF™ platform ensures that results generated at the discovery stage on the AXF™ Pathfinder can be re-produced seamlessly in clinical production volumes in a range that is suitable from small disease populations all the way up to full pandemic scale.

A single process geometry across different scale devices (same shear, same physics and same technology) facilitates seamless scale-up of formulations.

Ready cGMP certified equipment and processes for regulatory compliance.

Straightforward setup; global operator training; easy operation and maintenance for minimised downtime; aftersales technical support.

Full formulation development support at every stage if required.

Customised cGMP Solutions

With extensive formulation and manufacturing experience, our nano medicines formulations and engineering teams can help you through your entire journey from development to manufacturing.

We will:

- work with you to rapidly optimise formulation development increasing your speed to market
- work with you to design a pilot and manufacturing unit tailored to your capacity and product specification requirements
- execute technology transfer, with a process guarantee as appropriate, to allow you to take advantage of Micropore's AXF™ in manufacturing
- support you in your regulatory compliance goals
- develop a long term partnership maintains consistent levels of manufacturing performance as your market grows

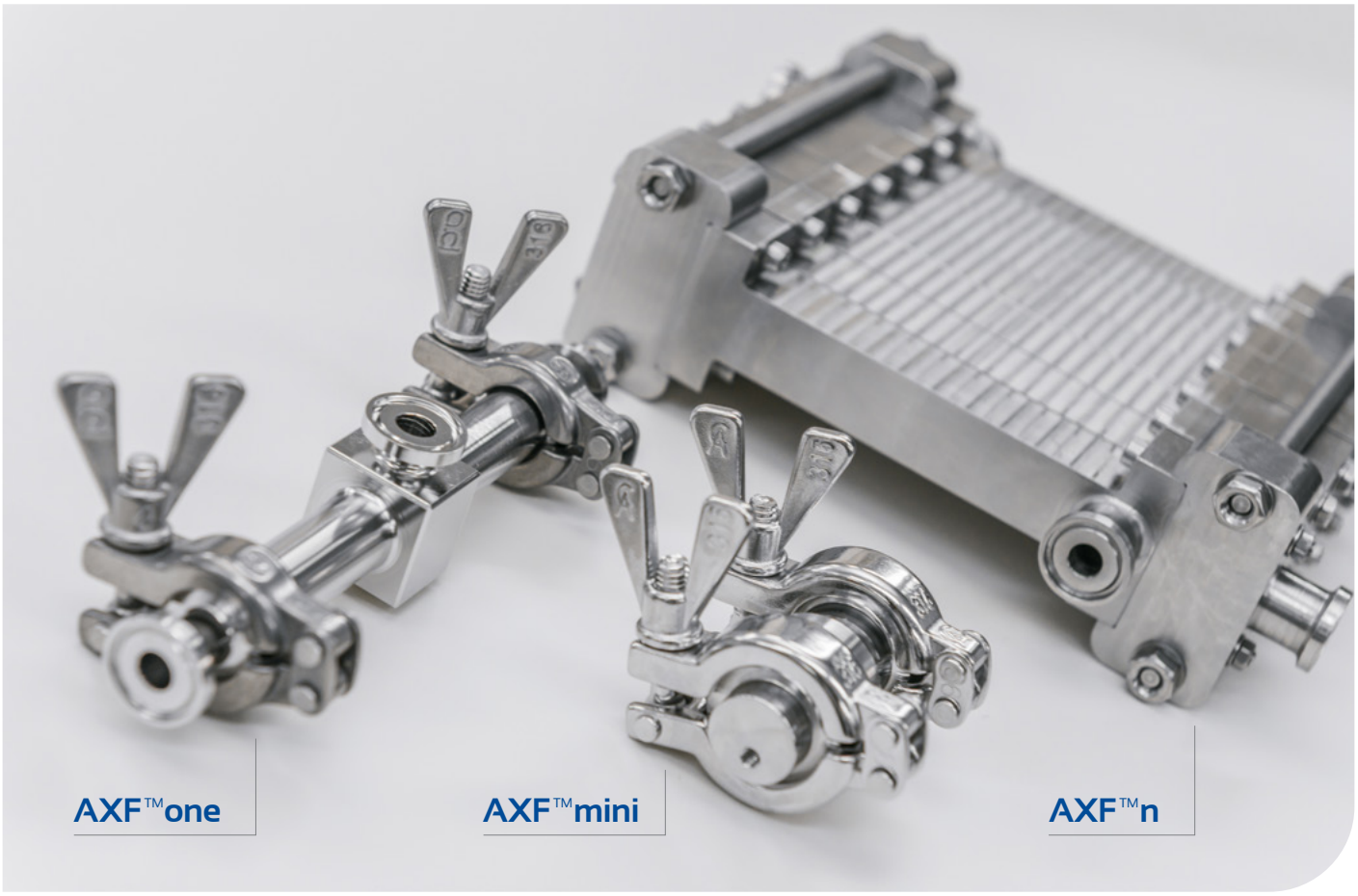
Regulatory Compliance

Micropore's AXF™ platform was designed to enable the clinical and commercial manufacturing of genomic medicines. It is manufactured under a Quality Management System certified to ISO9001.

Micropore Technologies has an established track record of providing timely support to help our customers meet country- or region-specific regulatory requirements needs.

About Micropore Technologies

Micropore's patented AXF™ micro-mixing technology was invented by Professor Richard Holdich, former Head of the Chemical Engineering Department at the internationally respected Loughborough University in the UK. Micropore Technologies was founded in 2003 to commercialise this unique new technology and now operates globally with a headquarters in the north east of England and offices in the USA and India; with distributors in South Korea, Japan and Australia.



The current range of Micropore Technologies AXF™ devices allows for seamless scaleability from Discovery to large scale Manufacturing.

ATA SCIENTIFIC instruments

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