

RELAZIONE TECNICO ILLUSTRATIVA

Lo strumento che Alfatest s.r.l. intende offrire è un **Automated Nanoparticle System (ANP - Sunshine)** della **Particle Works**, il quale utilizza la tecnica microfluidica del Flow Focusing e permette la produzione di nanoparticelle polimeriche e/o lipidiche per applicazioni di drug delivery.

Lo strumento presenta le seguenti caratteristiche tecniche:

- ✓ Permette la sintesi di nanoparticelle lipidiche e/o polimeriche di diversa dimensione, da 40 ad 800 nanometri, con un'elevata monodispersità (PDI di circa 0.1-0.2).
- ✓ Lo strumento è dotato di 4 linee di pompaggio a siringa indipendenti, controllate da un unico software, i cui materiali a contatto con il campione sono PTFE, vetro e/o Peek, pressione di esercizio 0-10 bar e risoluzione di 0,1 bar.
- ✓ È dotato di due valvole a 6 porte e 2 posizioni, ad alta resistenza chimica.
- ✓ Può produrre nanoparticelle in continuo attraverso la microfluidica, raggiungendo portate totali di fino a 24 litri al giorno.
- ✓ Può produrre in modalità protocollo fino a 10 preparazioni di nanoparticelle con altrettante condizioni di flussi differenti (Flusso totale e rapporti dei flussi) senza l'intervento di un operatore.
- ✓ Capacità di produrre volumi di soli 200 microlitri fino a 24 Litri/giorno senza modificare la microfluidica di preparazione, garantendone uno scale/up produttivo semplice e rapido.
- ✓ Il sistema permette di aumentare la pressione nelle bottiglie di alimentazione per facilitare l'aspirazione di eventuali solventi o soluzioni viscosi.
- ✓ Le microfluidiche compatibili con il sistema sono riutilizzabili e lavabili, composte di vetro e/o quarzo.
- ✓ Il sistema è in grado di eseguire dei protocolli di lavaggio efficace tra una preparazione e quella successiva, con elevata compatibilità a solventi come Cloroformio, THF, Etanolo, Acqua.
- ✓ Il sistema è dotato di un raccogliatore automatico di frazioni e della tecnologia "head and tail cut", minimizzando i volumi morti e evitando contaminazioni di differenti preparazioni.

La fornitura proposta comprende:

- ✓ una garanzia di base di 12 mesi;
- ✓ aggiornamenti del software;
- ✓ installazione e collaudo dello strumento con personale qualificato in sede.

Inoltre sono compresi:

Hardware & Software

- 2x PW Quad Pump modules (4 independent flow channels)
- 1x Pressurized Fluid Store (PFS) which includes:



- 4x 250ml bottles and caps
- Tubing to allow connection to customer house low pressure air or N2 supplies

- 1x Automated Sample Valve (ASV)
- 1x Automated Collector
- FCC Nanoparticle software installed on System Controller PC which includes:
 - Monitor, keyboard and mouse
 - Microsoft Windows
 - Preloaded with PW Flow Control Centre (FCC) Software & Protocols
 - Powered USB hub
- 1x Chip Docking station

Essential Accessories

- 4x PW Quad Pump Red Syringe pairs (2.5ml & 5ml) for fluid pumping from 50 µl/min to 10 ml/min
- Calibrated Tubing & Chip Kit which includes:
 - 2x Interfaces, 4x Connectors, 1x 100µm Junction Chip & 1x 190µm Junction Chip
 - PW Quad Pump inlet tube fittings for connection to PFS
 - 2x 5 ml sample loop for ASV
 - 2x 10 ml sample loop for ASV
 - ASV fittings set
 - PFS Pneumatic Adaptor Pack

Microfluidic Chips

- 1x Junction Chip (100 µm etch depth)
- 1x Junction Chip (190 µm etch depth)
- 2x Junction Chip (275 µm etch depth)
- 2x 5 Input Chip 3D (150 µm etch depth)
- 2x Micro Mixer Chip



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FIRMA

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Particle Works

Automated Nanoparticle System



Optimize your formulation and process development with the Automated Nanoparticle (ANP) System.

The ANP System is designed to speed up your process development through greater efficiency and precision when generating nanoparticles at small-scale with reduced amounts of precious cargo. Built around our reusable and robust microfluidic chips, you can reproducibly and reliably generate particles for a broad range of applications from 40 nm to 800 nm with ease.

Simple to set up and featuring walk-away automation, the System can run 15 experiments in less than 20 minutes, letting you get on with other tasks in the lab at the same time. Its flexibility means you can change critical parameters easily that are logged and can be exported in common formats for traceability.



Monodispersity

Excellent PDI and encapsulation efficiency.



Scalability

From 200 μ l to continuous production.



Flexibility

Easy to set up and modify parameters.



Speed

Rapid optimization timeframes.



Cost saving

Reduced reagent use and reusable chips.



No IP Licensing

No tying in to licencing models.

We've seen what's possible when brilliant minds come together to focus and find the answers. You continue to inspire us with the incredible work you're doing and we champion your commitment to push the boundaries of science.

We care deeply about the revolutionary change our technology can bring and the powerful impact it will have. Let's shape the big picture together, one particle at a time.

System overview

The ANP System has been designed for nanoparticle process development and pre-clinical production. It revolutionizes nanoparticle synthesis by providing reliable, reproducible and higher throughput production, whether you are making liposomes, lipid nanoparticles (LNPs) or polymer-based nanoparticles.

The platform is easy to use, automated, and highly modular, incorporating our precision engineered microfluidic technology and utilizing our in-house designed and fabricated, reusable microfluidic chips for controlled convergence of fluids within the pathway. It can automate dozens of experiments for screening and optimization, utilizing a fixed pair of reagents in sample loops up to 10 ml. It can also operate in continuous production mode, facilitating production of tens of liters per day.

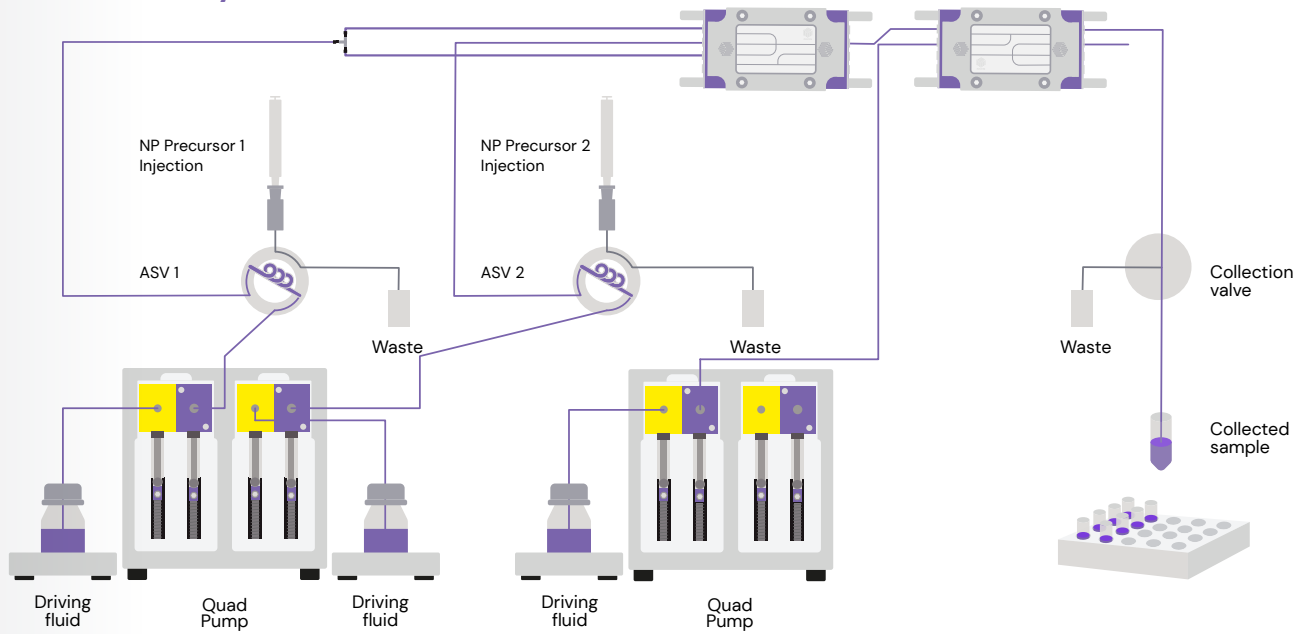
System modules:

- **Quad Pump** – an automated two-channel syringe pump designed to aspirate fluids from a source bottle and dispense into the system, ensuring accurate dosing, continuous flow and consistent nanoparticle generation.
- **Automated Sample Valve (ASV)** – chemically resistant valves (6 port, 2 position) enabling direct injection of fluids into interchangeable sample loops.
- **Pressurized Fluid Store (PFS)** – to facilitate operation at high flow rates in continuous production mode.
- **Automated Collector** – for automatic sample collection, supplied with 2 ml and 8 ml vial racks.

Particle size	Particles ranging from 40 nm to 800 nm.
Particle monodispersity	Extremely monodisperse with PDI ~0.1 – 0.2.
Sample volume	200 µl to continuous production.
Speed	10 samples collected within 15 minutes.
Automation	The system software allows easy creation of protocols to automatically process many different experiments from a single sample loading which will be run without human interference.
Flexibility	The modular system can be paired with a range of glass chips and sample loops tailored to your specific application. Can be used to manufacture a wide range of nanoparticles from LNPs to polymers.
Scalability	From screening to production using same chip allowing production volumes from µl to liters per day.
Budget-friendly	Excellent encapsulation efficiency coupled with very low sample use and reusable glass microfluidic chips provide a very cost effective and environmentally responsible solution.

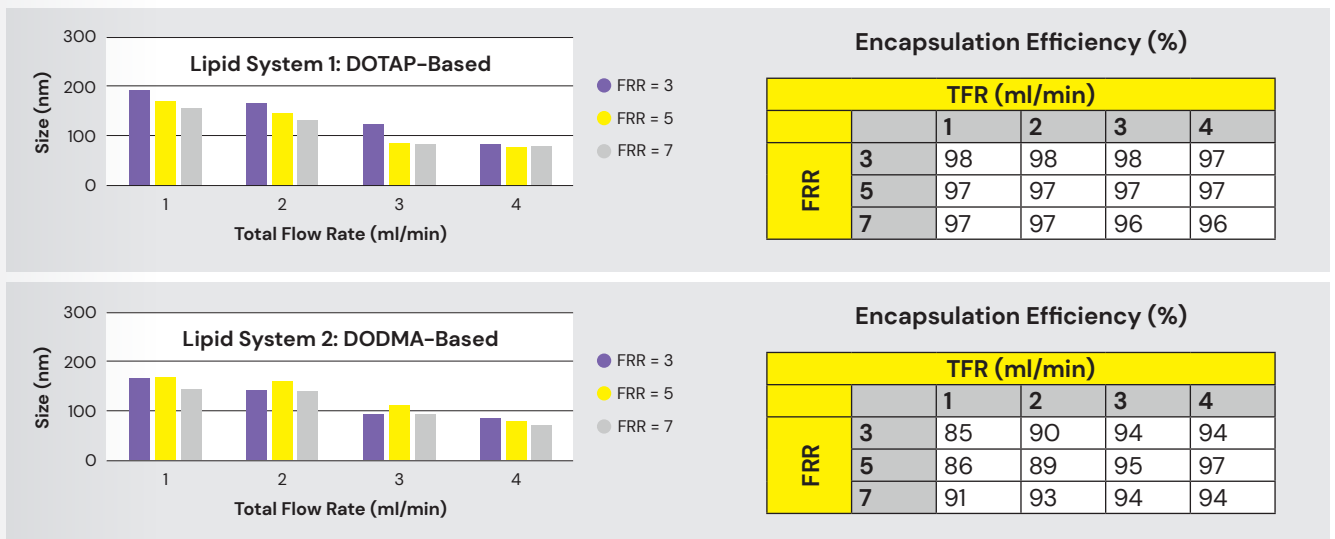


How the ANP System works:



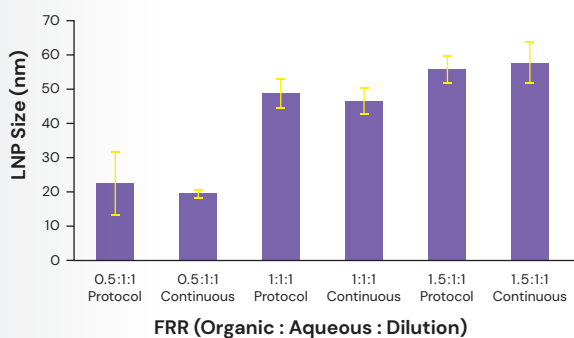
Let the data speak for itself:

The ANP System enables control over LNP size and Encapsulation Efficiency. Particle size can be controlled by total flow rate (TFR) and flow rate ratio (FRR), maintaining high encapsulation efficiency throughout, as shown in the data below.*

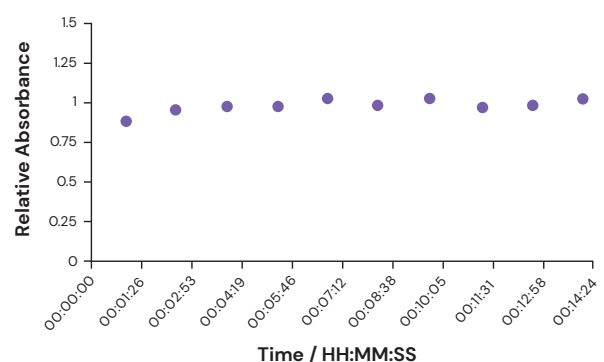


*Data courtesy of Phosphorex

LNPs produced using a range of FRRs from either protocol (2 ml sample) or continuous production mode (> 20 ml sample), using a 3 ml/min TFR. The LNP sizes differed by < 7 nm between protocol and continuous mode, PDI < 0.2, with S.D. = 0.01 (represented by error bars).



The graph below shows 10 samples collected within 15 minutes, from a single protocol on the ANP System, with high sample concentration consistency between experiments.



Rooted in microfluidics

Under Dolomite Microfluidics (part of Blacktrace Holdings Ltd), we've been at the forefront of microfluidics and working with particles for nearly two decades. We've listened to our customers and launched a dedicated particles brand, designing and building game-changing particle engineering platforms which will allow you to produce nanoparticles with unrivalled precision, consistency, & control, whilst reducing your development time and cost.

Advantages of microfluidics

Continuous flow process provides a small and consistent reaction window as fluids converge precisely providing:

- Unparalleled consistency of particle size and monodispersity.
- Higher encapsulation efficiency with controlled payload release.
- Higher reproducibility and linearly scalable processes.
- Lower sample volumes and reduced waste, ideal for screening and development.
- Negates particle damage caused by mechanical mixing.
- Faster, easier to optimize protocols.
- Scalability – produce μl to liters with the same chip.

What makes us unique is our combined capabilities: a strong history of particle engineering, scientific knowledge, microfluidic expertise, and in-house chip design and fabrication. We also offer a proof of principle service, offering you the opportunity to test your protocol and Active Pharmaceutical Ingredients (APIs) prior to purchase.

We pave the way for particle perfection – delivering unrivalled accuracy, quality, consistency, and efficiency: from our technology and custom studies to our customer support.

Engineering a future worth experimenting for together

As we look to the future, we have more exciting platforms in our product pipeline that will take you all the way from formulation screening, and protocol development to GMP scale-up and large-scale production.

Let's zoom in to make big change, one particle at a time.



Your pathway to particle perfection



Screening



Protocol development



Initial scale-up



Production

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