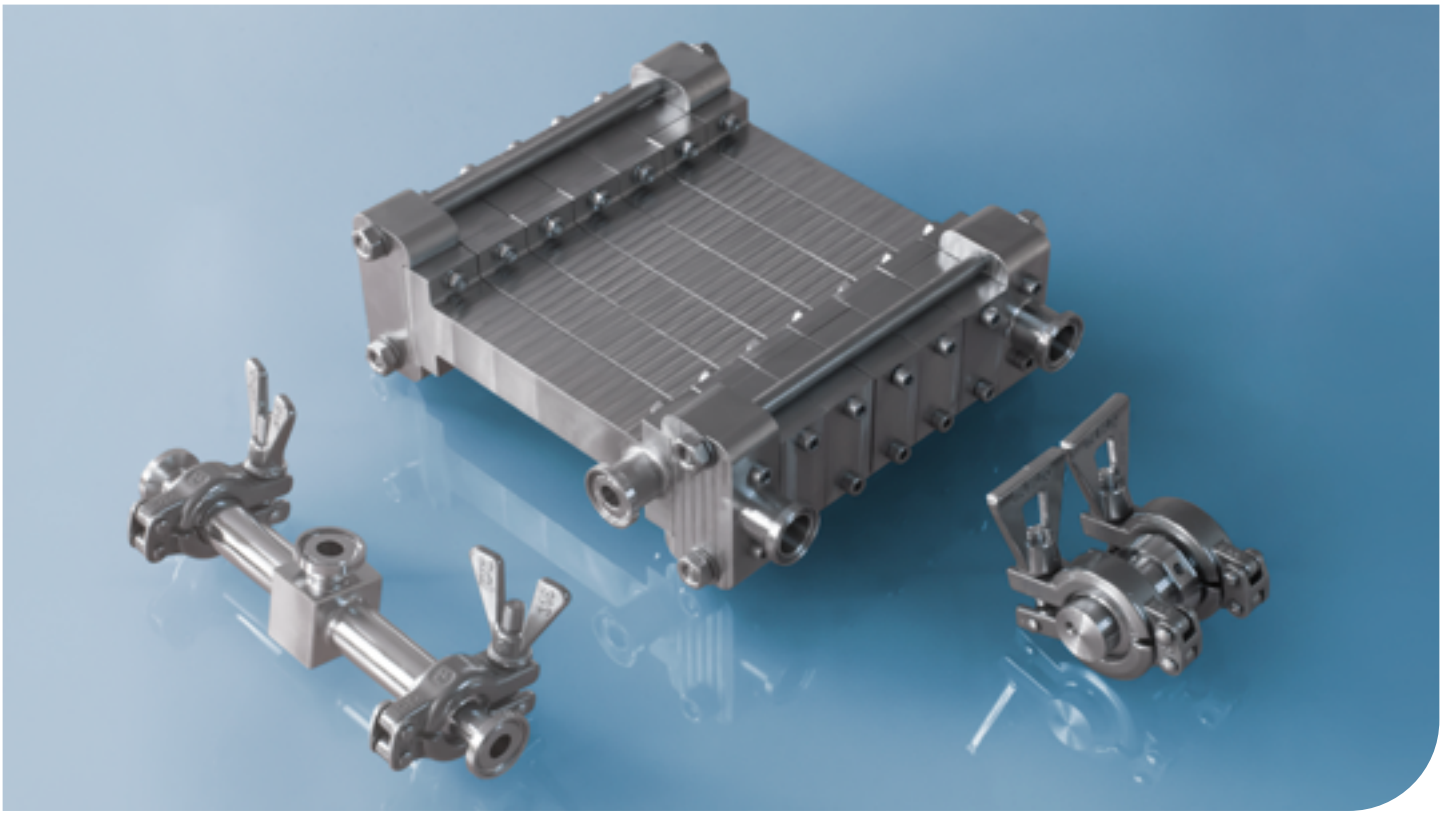
Micropore Technologies

# AXF-Series



## Precision Particle Engineering

Micropore offers a scalable, GMP ready, platform for developing and manufacturing microparticles, capsules, lipid nanomaterials & crystals at tightly controlled sizes.

### Common features of all devices

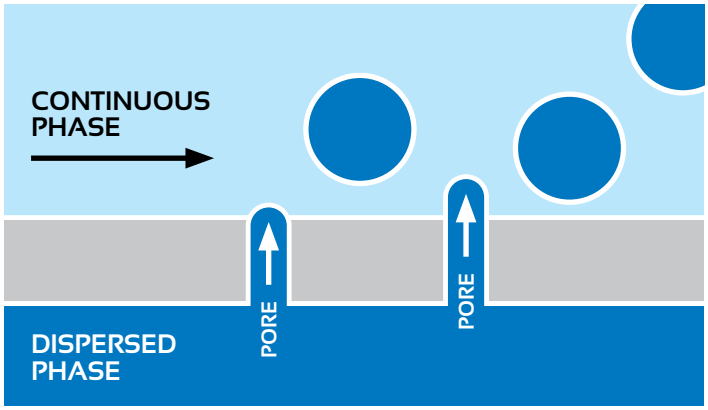
Micropore's technology uses precision engineered, stainless steel membranes together with other stainless steel components. The results of using this particle formation and mixing technology are clear:

1. Reproducibility and reliability of the process
2. Narrow size distributions reducing waste and the need for downstream processing
3. Reduced energy usage compared to high energy mixing and homogenisation
4. Gentle processing preserves the integrity of fragile materials
5. The robustly engineered process minimises consumables
6. Option for integration with Process Analytical Technology (PAT) for in-process control

# Microspheres & microcapsules

Emulsification

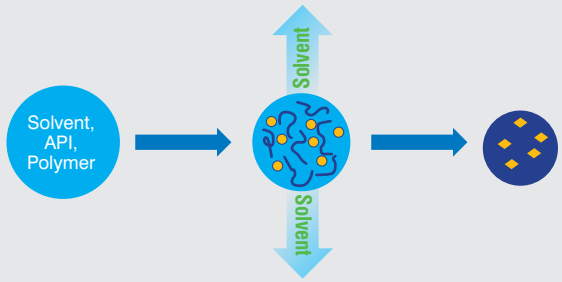
Encapsulation

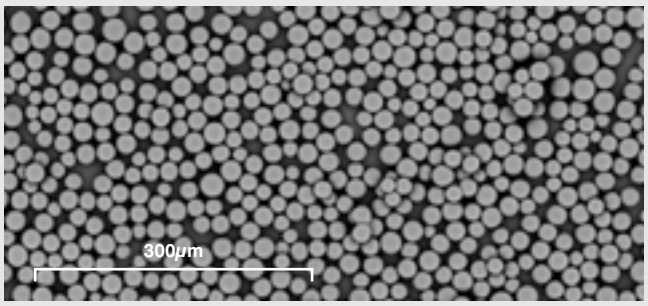


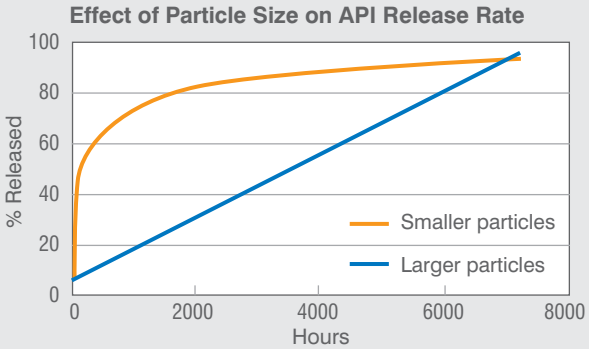

In this application of Micropore's technology the membrane is used to control the size of microspheres and microcapsules produced by providing a gentle shear force to detach the droplets as they form through the pores.

## Example applications

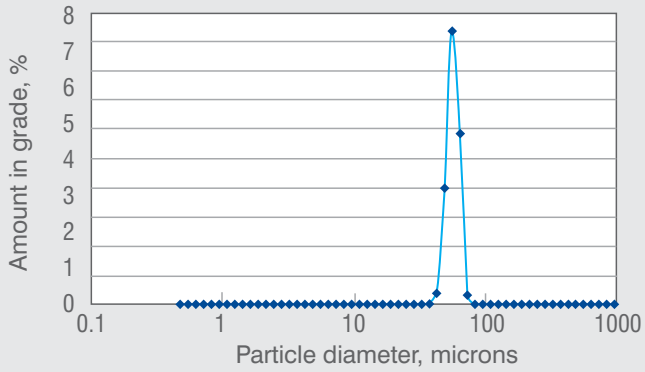
### Controlled release microspheres

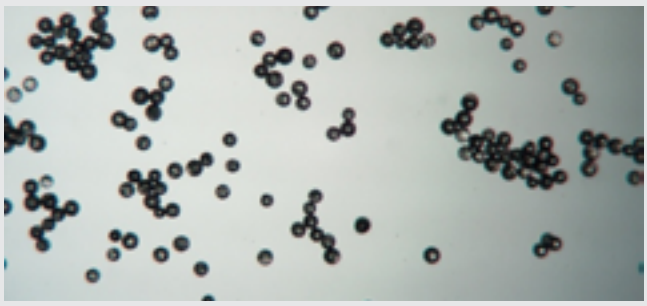


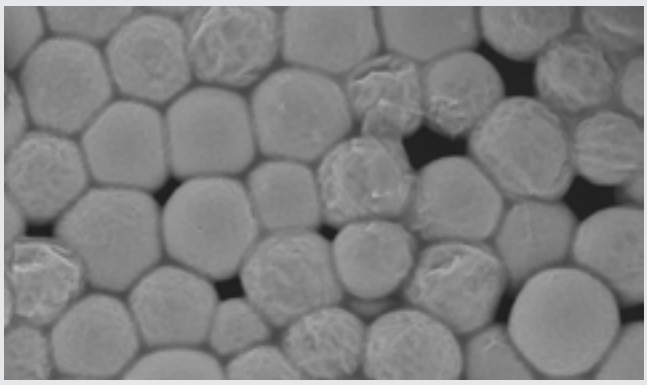




### Interfacial polymerisation





### Controlled release microsphere benefits

1. Precise size control enabling a near zero waste process
2. Reduction/elimination of downstream sieving
3. Rapid product development through ease of scalability
4. Ease of GMP qualification: no moving parts, SS316 & PTFE construction

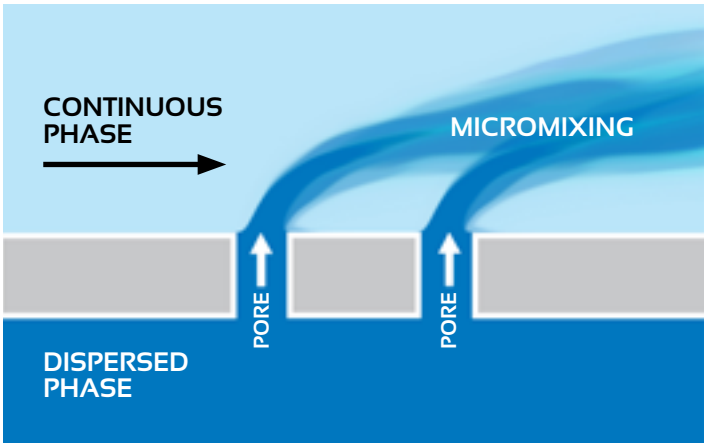
### Interfacial polymerisation benefits

1. Precise control over shell formation giving consistent release profiles
2. High encapsulation efficiency due to low-shear processing

# Micromixing

Bioengieering

Crystallisation

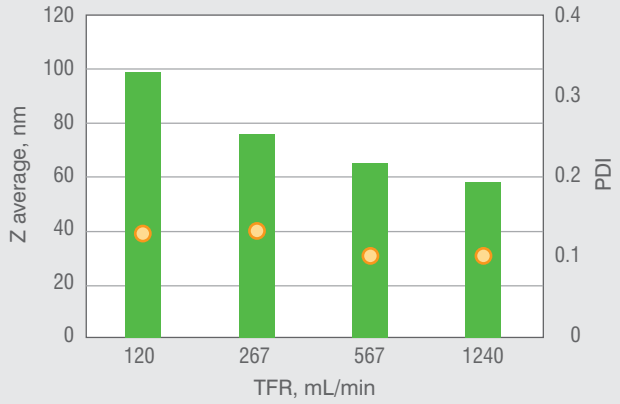


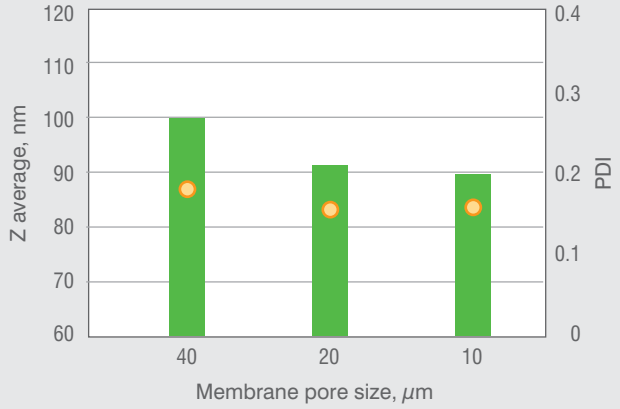

In this application of Micropore's technology the membrane is used to control the degree of micromixing to enable precise self assembly (in the case of liposomes or Lipid nanoparticles (LNPs), or to control solvent exchange (in the case of crystallisation).

## Example applications

### Liposome and LNPs

**LNP size control - flow rate**

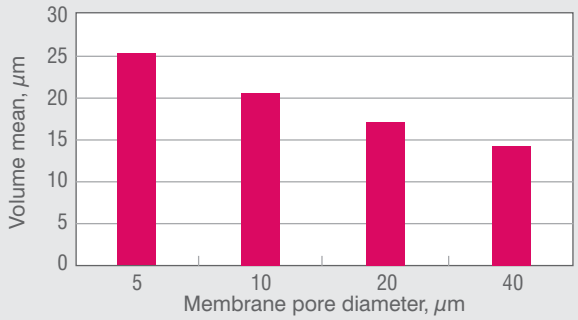


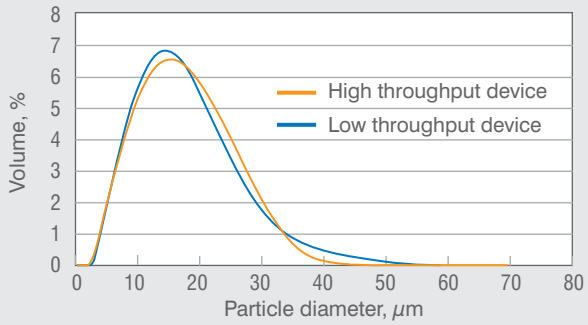

| TFR (mL/min) | EE (%) |
|---|---|
| Target | >90% |
| 100 | 91.04 |
| 300 | 97.10 |
| 500 | 98.08 |
| 500 | 97.84 |
| 500 | 98.23 |
| 500 | 98.51 |

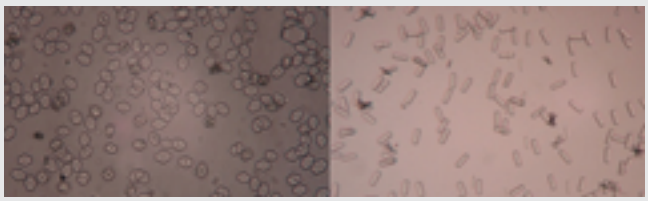
### API Crystallisation

**Effect of membrane pore diameter on particle size distribution of telmisartan, obtained by laser diffraction**

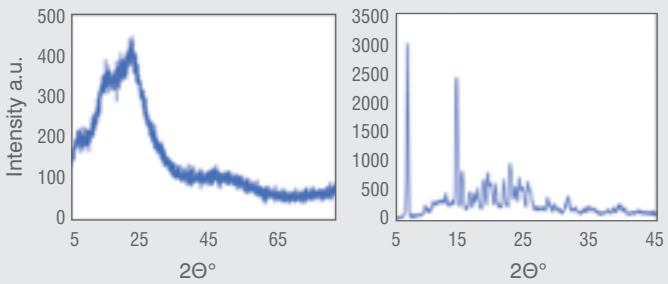



**Comparison of runs across scale up**



**XRPD patterns of telmisartan – control of crystallinity: amorphous to crystalline**



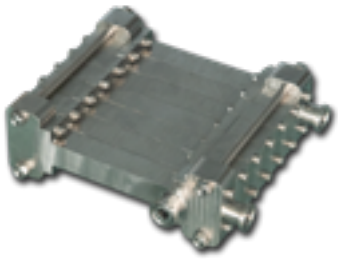
## Liposome and LNP benefits

1. Very high throughput from a compact device
2. Low energy; reduced truncated RNA species
3. Ease of GMP qualification: no moving parts, SS316 & PTFE construction

## API Crystallisation benefits

1. Precise control over crystal size, eliminating downstream processing
2. Control over morphology / polymorphism
3. Ability to produce amorphous APIs

# The AXF equipment range

| Product |  |  |  |
|---|---|---|---|
| | **AXF-Mini** | **AXF-1** | **AXF-N (configured as AXF-7)** |
| Production capacity (TFR) | 0.06 L/hr – 20 L/hr | 6 L/hr – 200 L/hr | <1,500 L/hr |
| Disperse phase hold-up volume | 0.1 mL | 5 mL | 20 mL |
| Continuous phase hold-up volume | 0.3 mL | 5 mL | 100 mL |
| Minimum disperse phase aliquot | 0.2 mL | 10 mL | 40 mL |
| Volume to achieve steady state operation | 0.2 mL | 5 mL | 30 mL |

- Small equipment footprint (<A4)
- Specifically designed for applications where high levels of hygiene, including GMP, are important*
- SS316 & PTFE parts for high material compatibility and simple sterilisation
- Elegant, robust, ultra-low maintenance equipment with no moving parts, that are easy to clean, for continuously manufacturing high quality emulsions
- Fed by low pressure pumps with options for contactless flow and gentle ingredient handling
- The internal tubular membranes are precision engineered with pores along their length to deliver continuous streams of near mono-dispersed droplets at controllable dimensions
- Throughput volumes from 0.06-1000+ litres per hour
- Low energy consumption and minimal processing wastage

*The Micropore AXF-1 model is also available in a non cGMP industrial configuration.

# Formulation development with Micropore

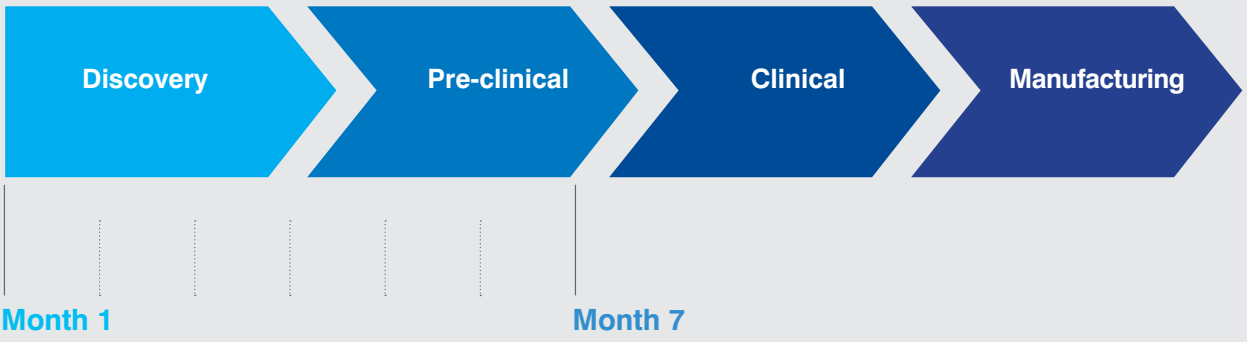
Partnership with Micropore can reduce your product development timelines, with experience of transferring to clinical studies within 7 months of initial engagement.

Micropore offer formulation development and small-scale sample production and analysis for microspheres, emulsions, capsules, crystals, and nanomaterials.

From short 2-week concept studies to full 16-week+ development programs, Micropore can determine appropriate formulations and operating conditions for producing products that meet the desired size, release, and loading criteria. Development programs Include provision of small test samples and a larger scale-up batch for further analysis or in-vitro studies.

**Improve your:**

- Development timelines
- Particle size and size distribution
- Encapsulation efficiency
- Drug loading
- Drug release rate kinetics and profiles
- Batch predictability
- Production times – no sieving
- Process understanding




**Supported at all stages by ongoing formulation support and training options**

Micropore Technologies Ltd. Wilton Centre, Redcar, TS10 4RF, UK Tel: +44 (0) 1642 438367
Micropore Technologies Inc, 2121 T.W. Alexander Drive, Suite 124, Morrisville, NC 27560, USA Tel: +1 (984) 344-7499
Micropore Technologies (India) Private Limited, 8th Floor, SLN Terminus, Survey No 133 Beside Botanical Gardens, Gachibowli, Hyderabad, 500032 Telangana, India Tel: +91 (0) 81064 54179
Email: service@microporetech.com **www.microporetech.com**

Micropore Technologies