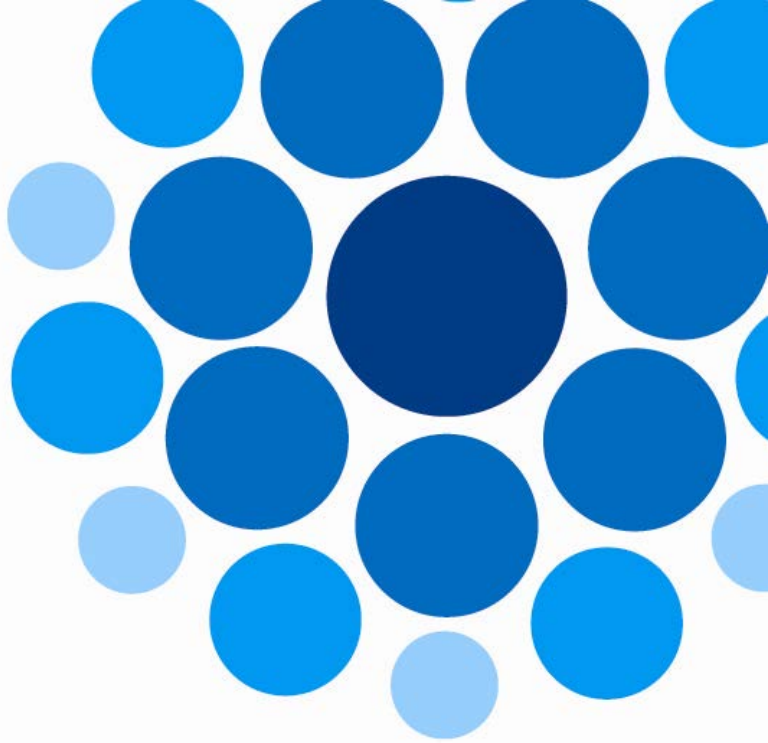


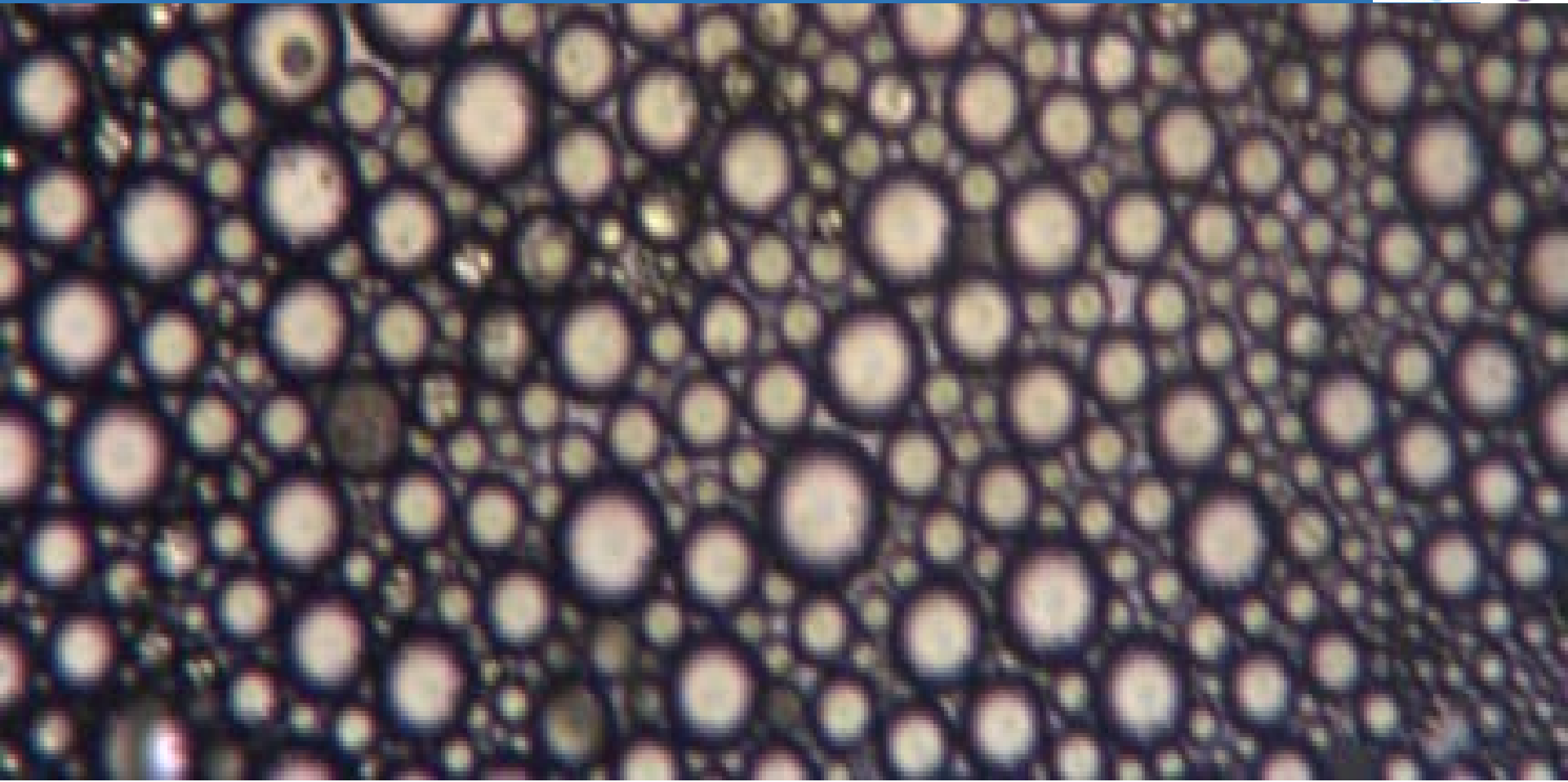
Micropore Technologies

“Partners in Precision Particle Production”

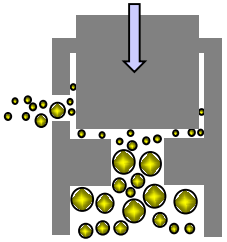
Dai Hayward FRSC
CEO

E: dai.hayward@micropore.co.uk
W: www.micropore.co.uk

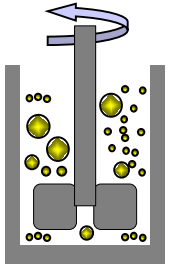
A typical emulsion



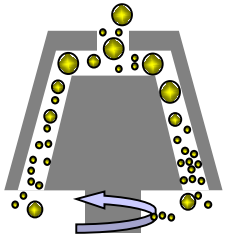
Making Emulsions – Conventionally



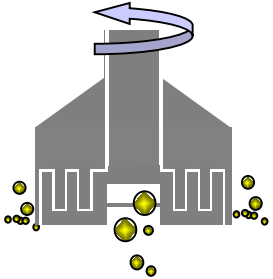
High-pressure systems



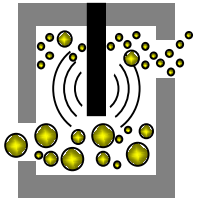
Stirring vessels



Colloidal mills



Toothed disc dispersing machines



Ultrasound systems

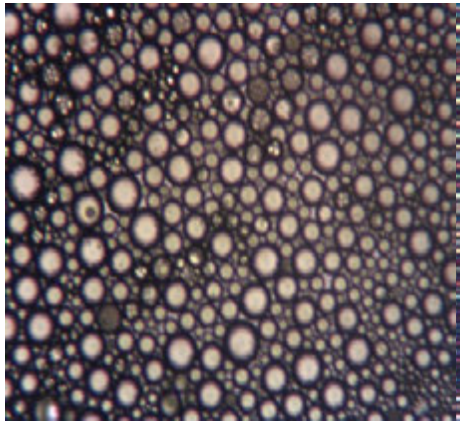
They all apply **more energy** than needed for the production of droplets

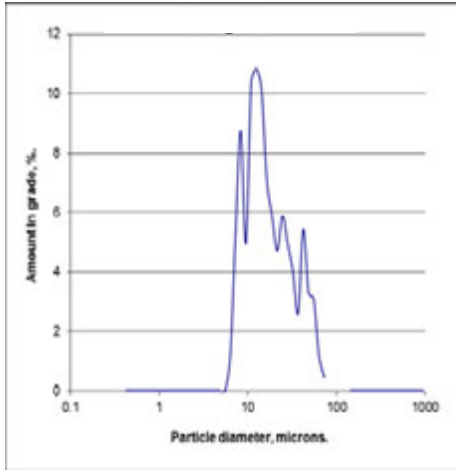
and

give droplets with **wide size distribution**.

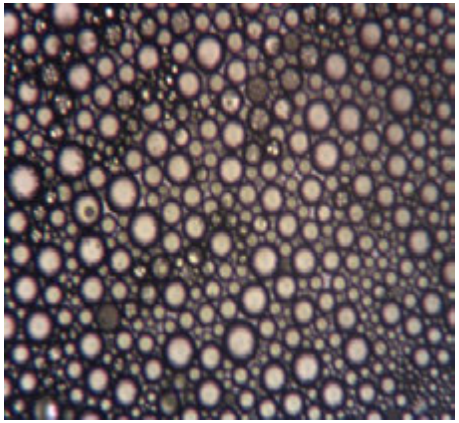
Karbstein H. and Schubert H. 1995

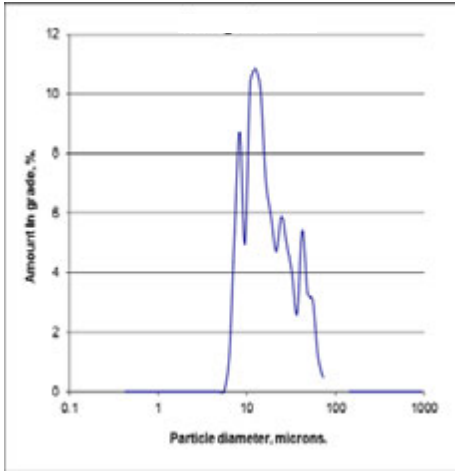
The Technology





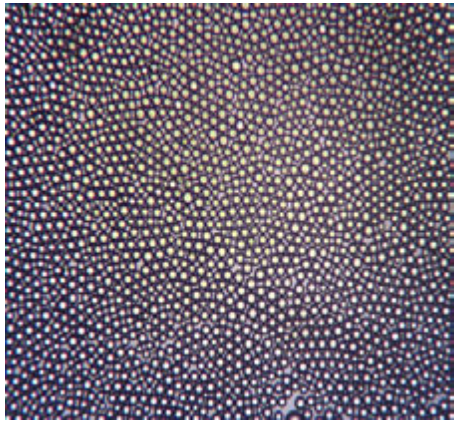
Why do we do it?

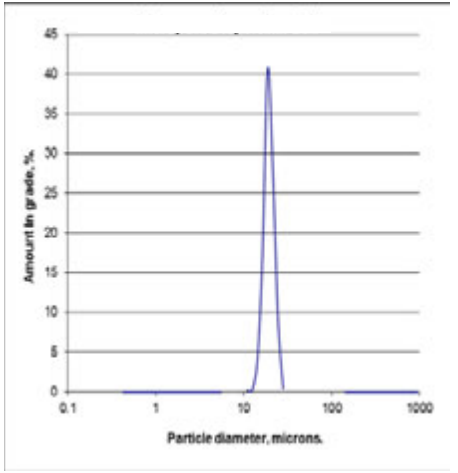




Homogenisation | **Membrane emulsification**

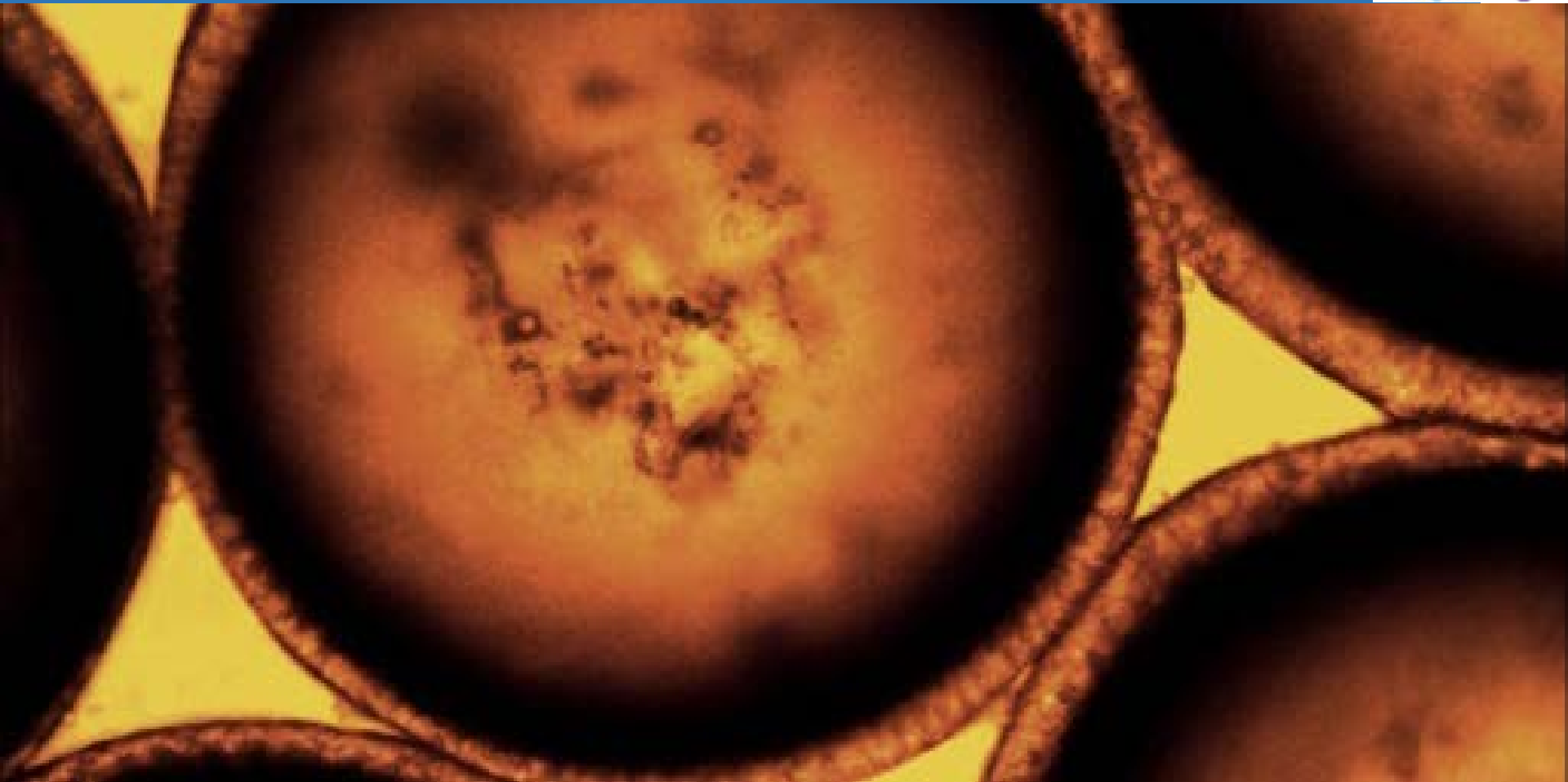
	Attribute	
Low ←	Controllability	→ V High
V High ←	Shear	→ Low / Medium
Wide ←	Size distribution	→ V Narrow
	Benefit	
Low ←	Yield	→ V High
Low ←	Activity retention	→ V High
High ←	Energy usage	→ Low



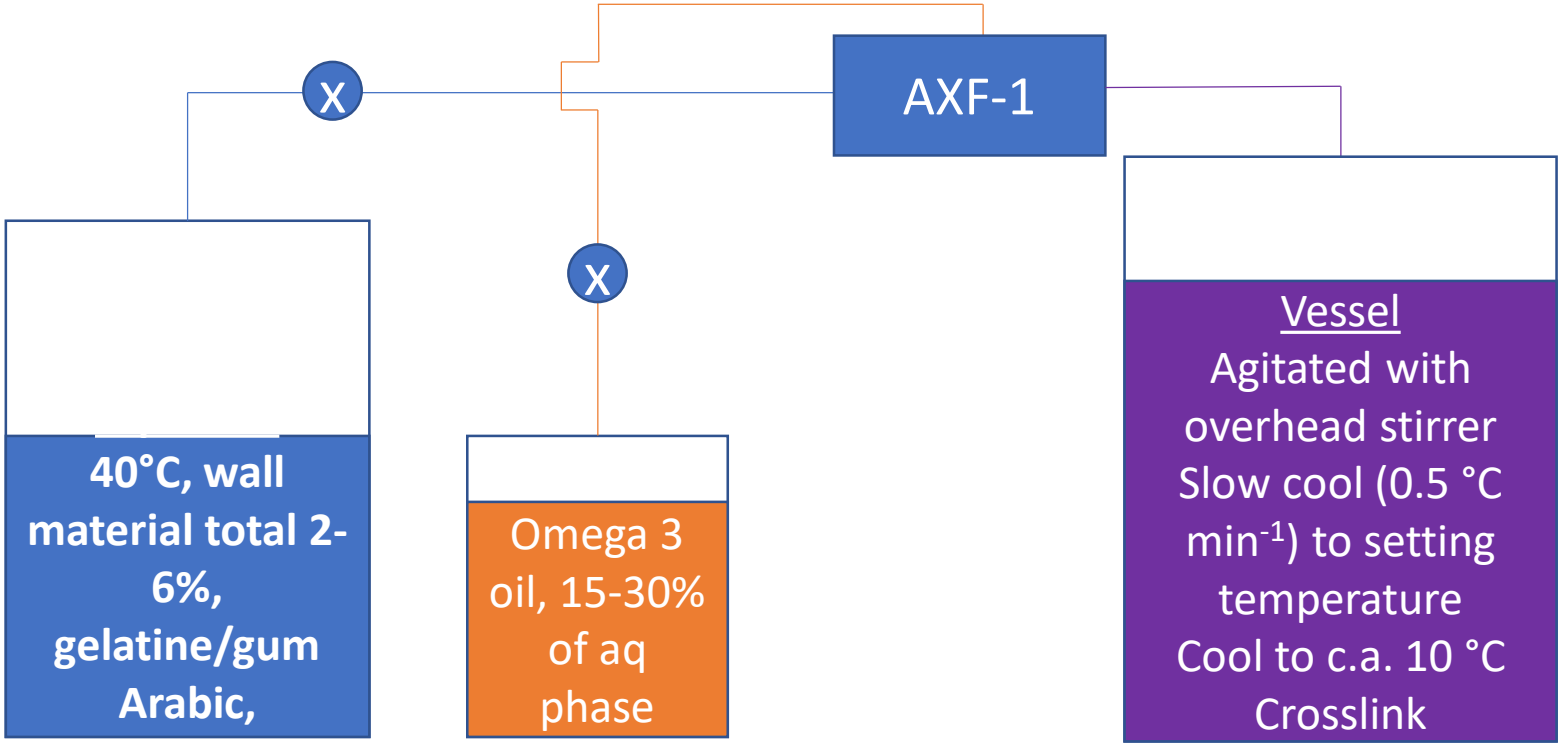


Formulation capabilities

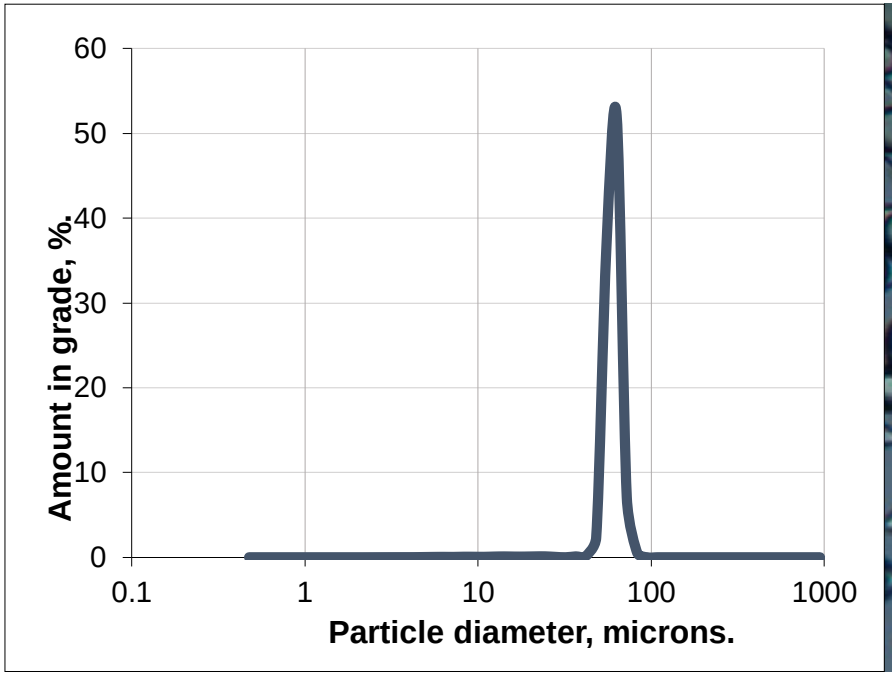
Applications in Encapsulation – Complex Coacervation

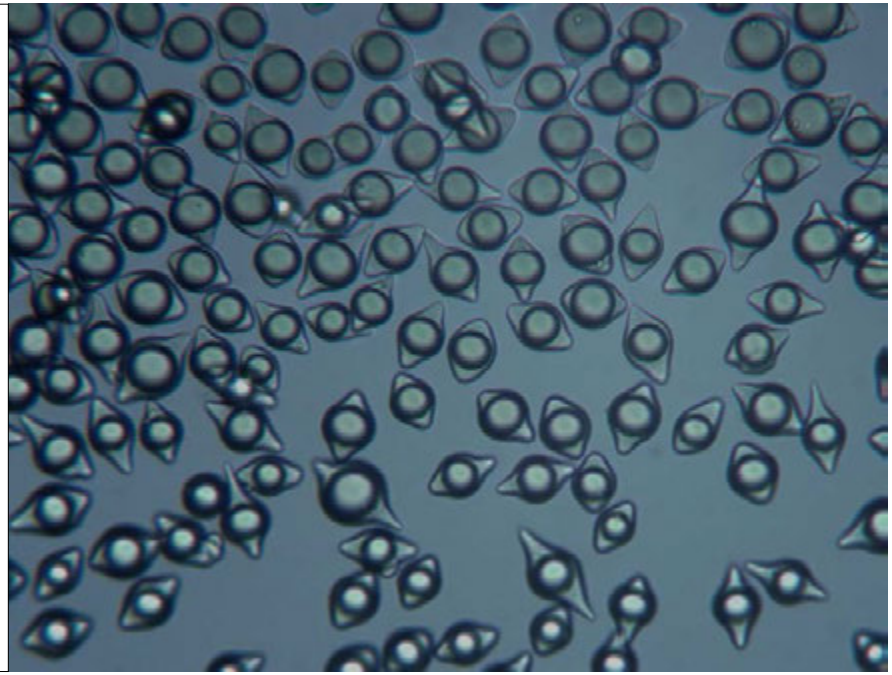


Micropore's method



Monodisperse capsules

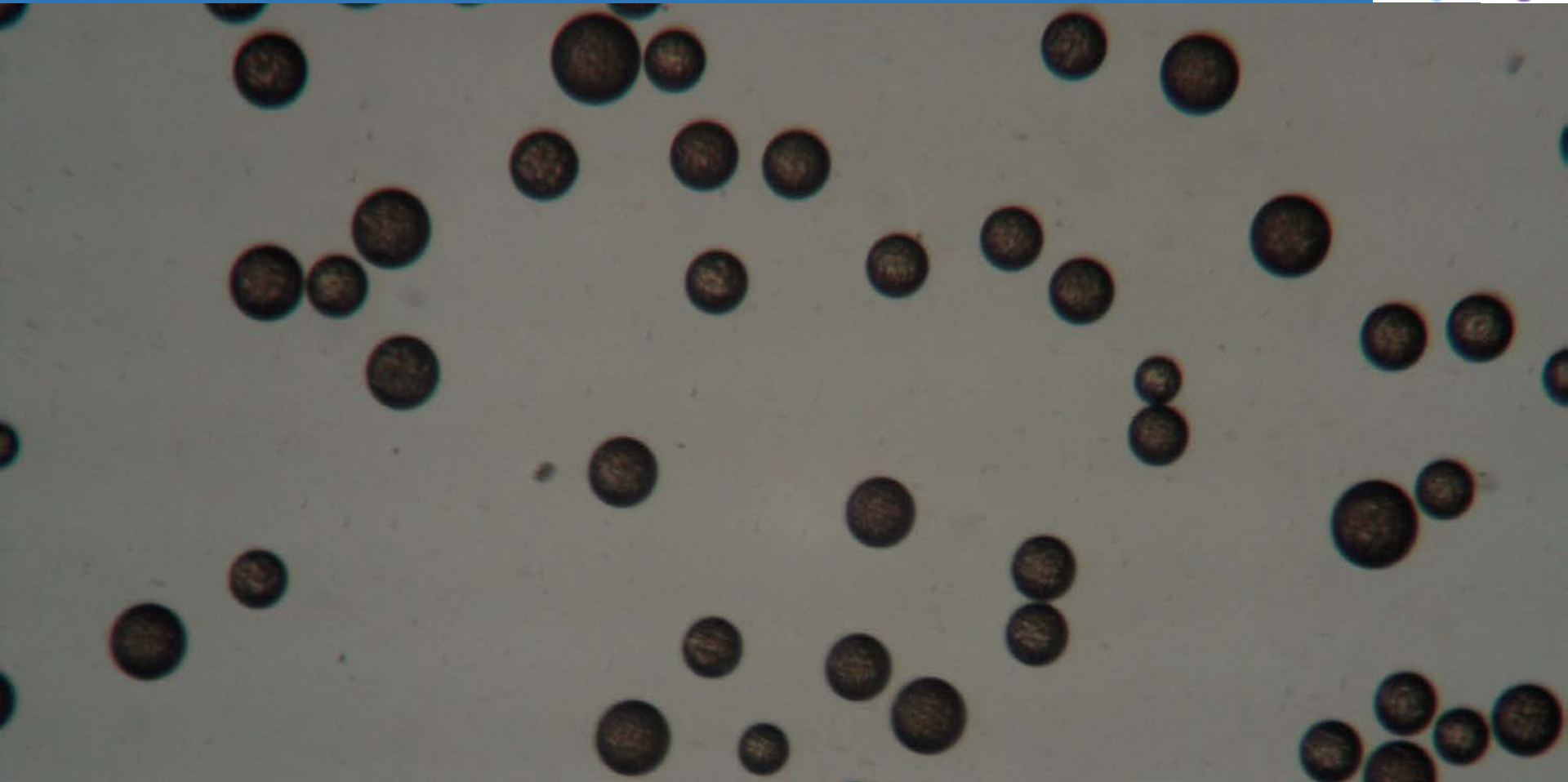




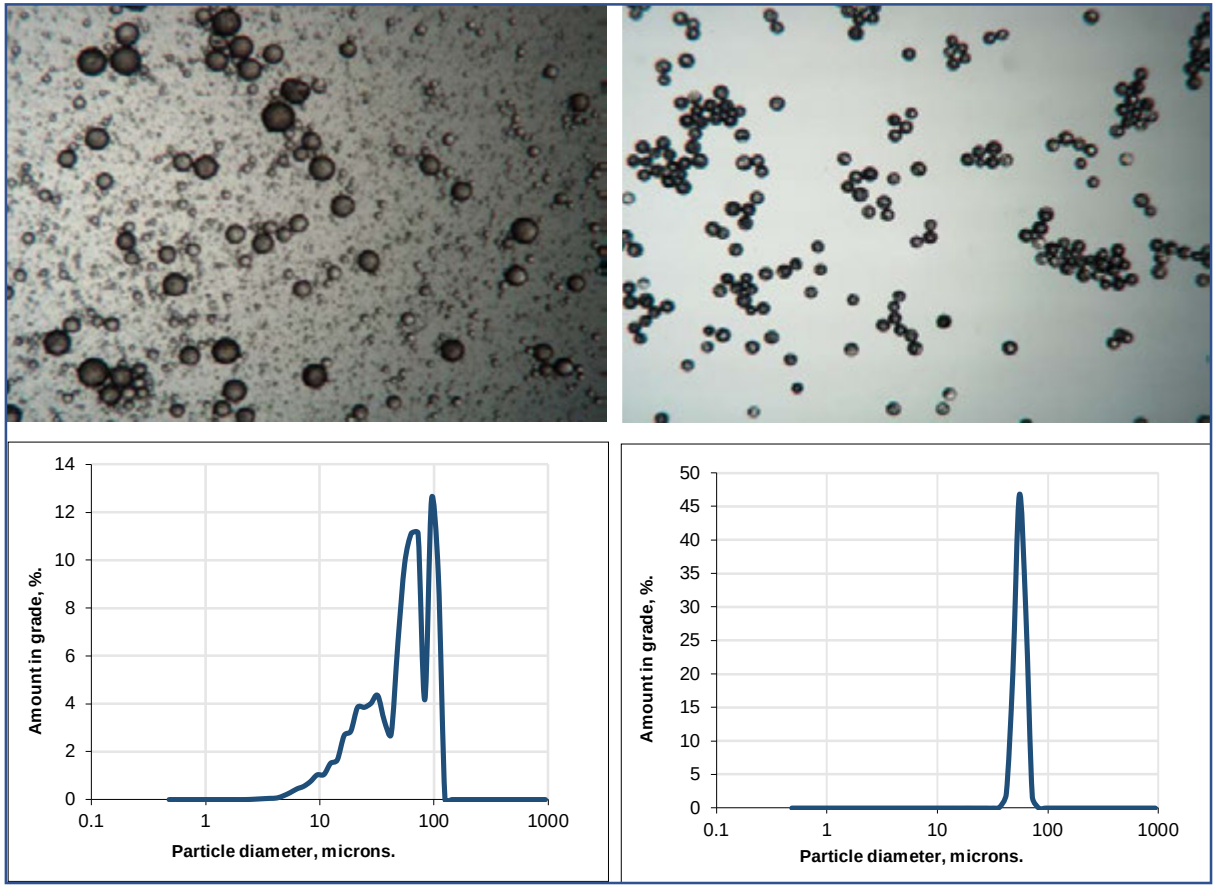
Volume Distribution	Diameter
D10	47.16 um
D50	52.26 um
D90	57.59 um

Statistical Analysis	
StDev	6.32
Span	0.20
CV	12.02%

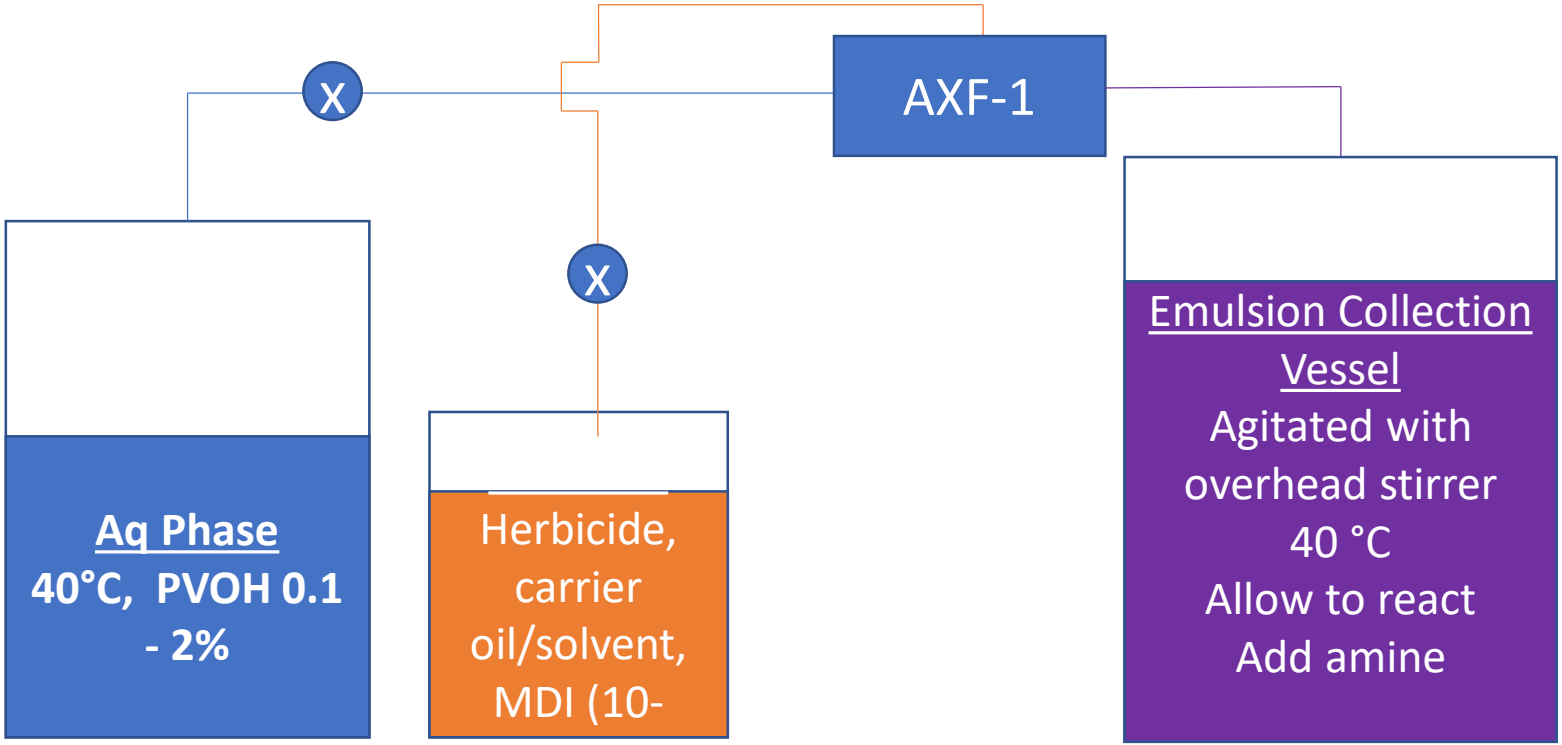
Applications in Encapsulation - Interfacial Polymerisation



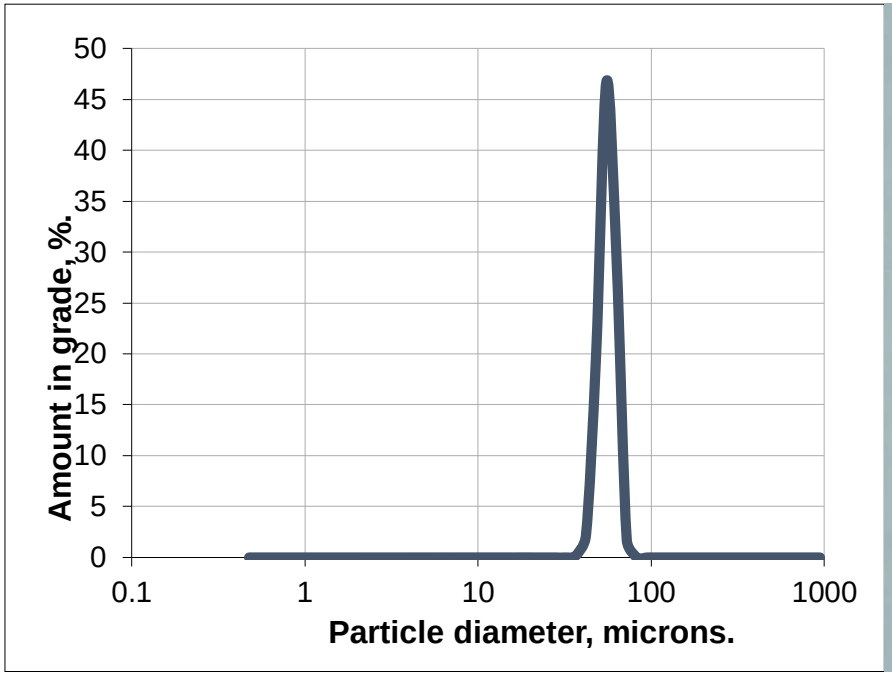
Monodisperse capsules – again!

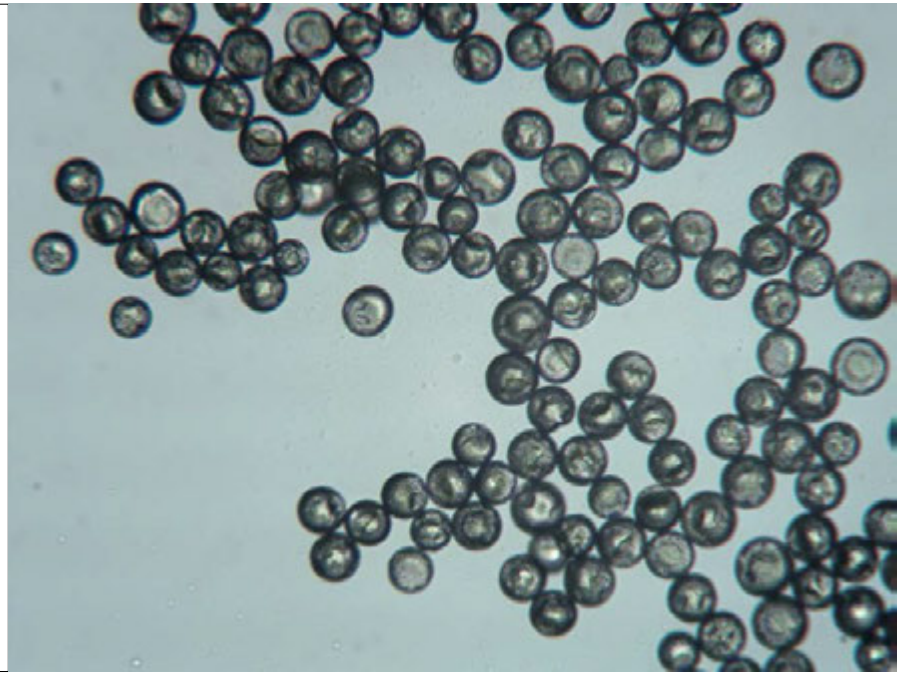


Micropore's method – Polyurea capsules



Monodisperse capsules – yet again!

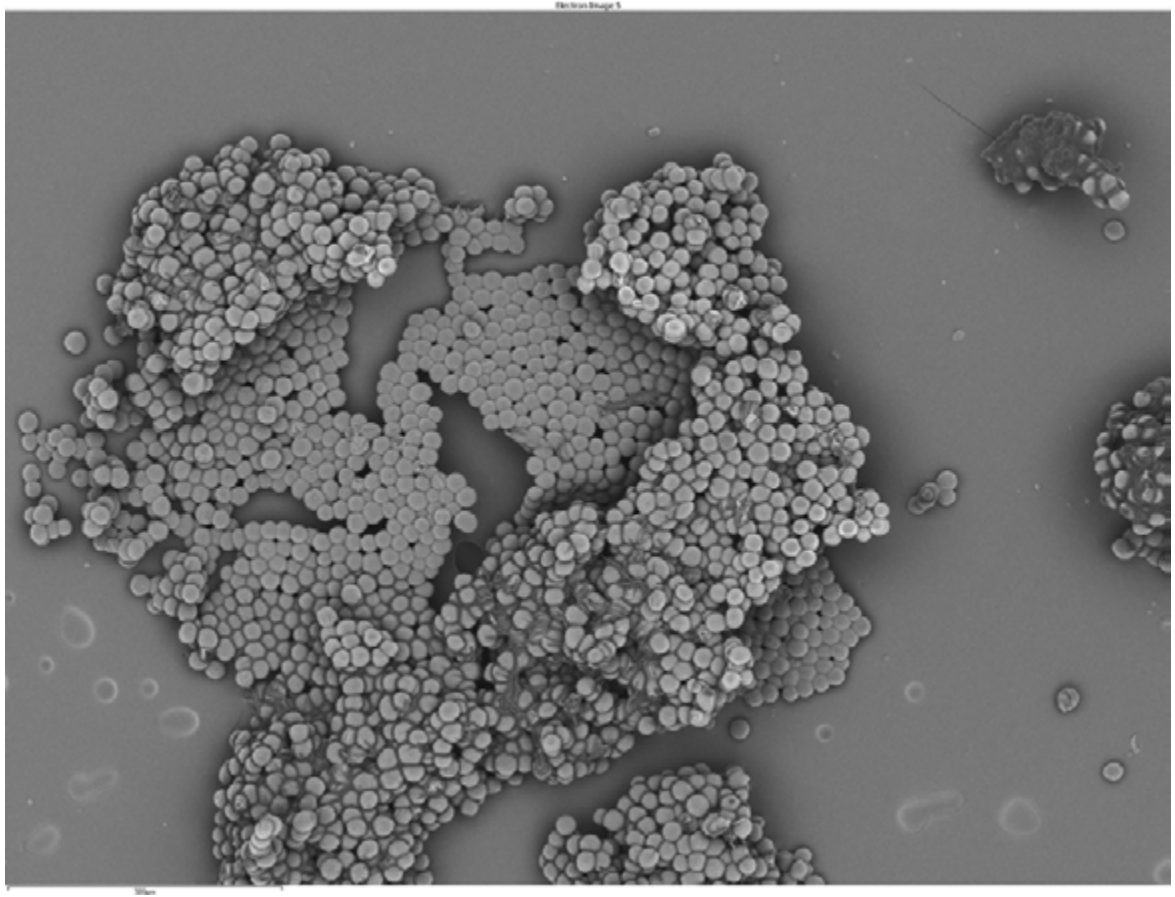




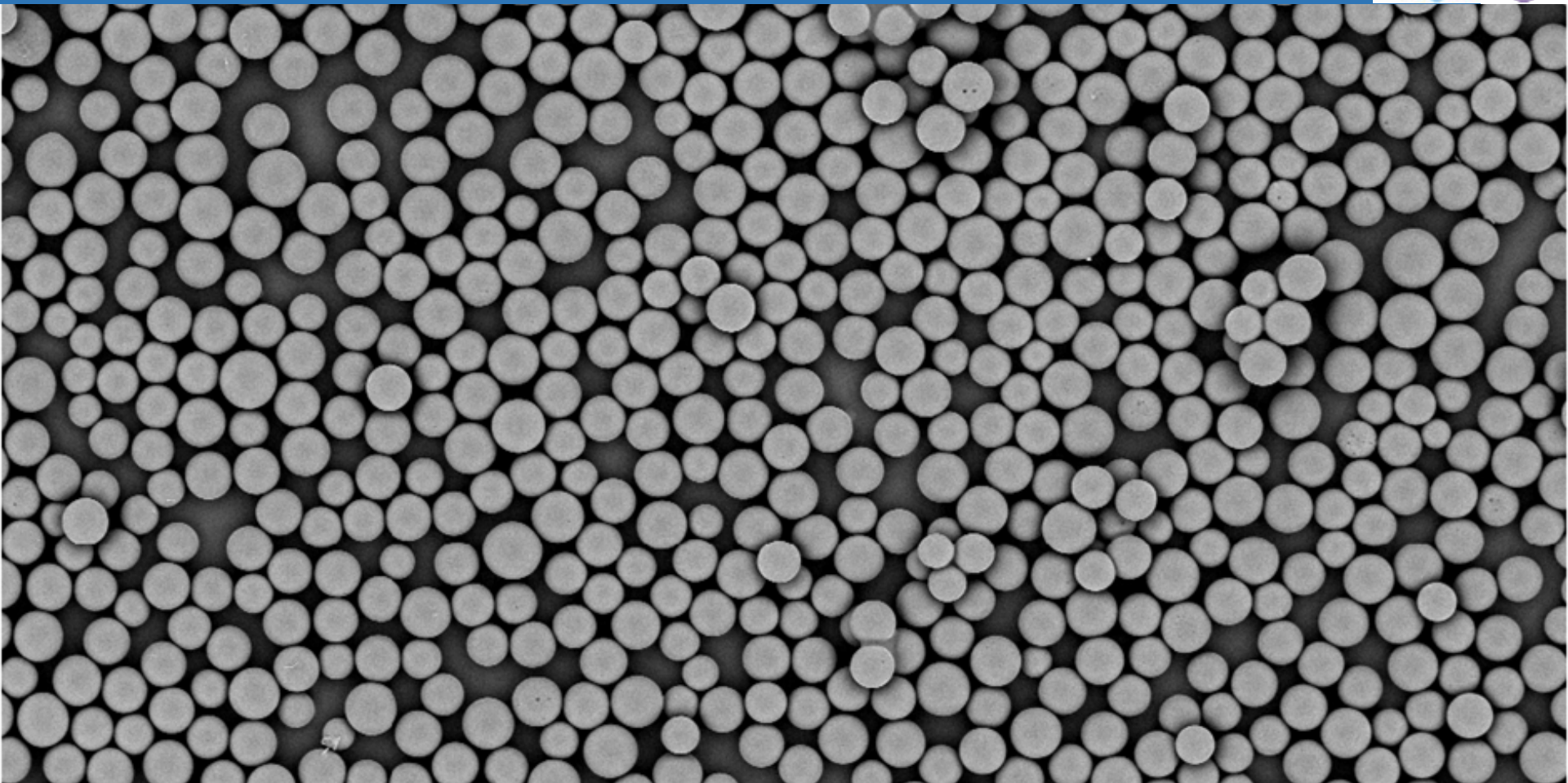
Volume Distribution	Diameter
D10	42.28 um
D50	48.19 um
D90	54.91 um

Statistical Analysis	
StDev	5.37
Span	0.26
CV	10.97%

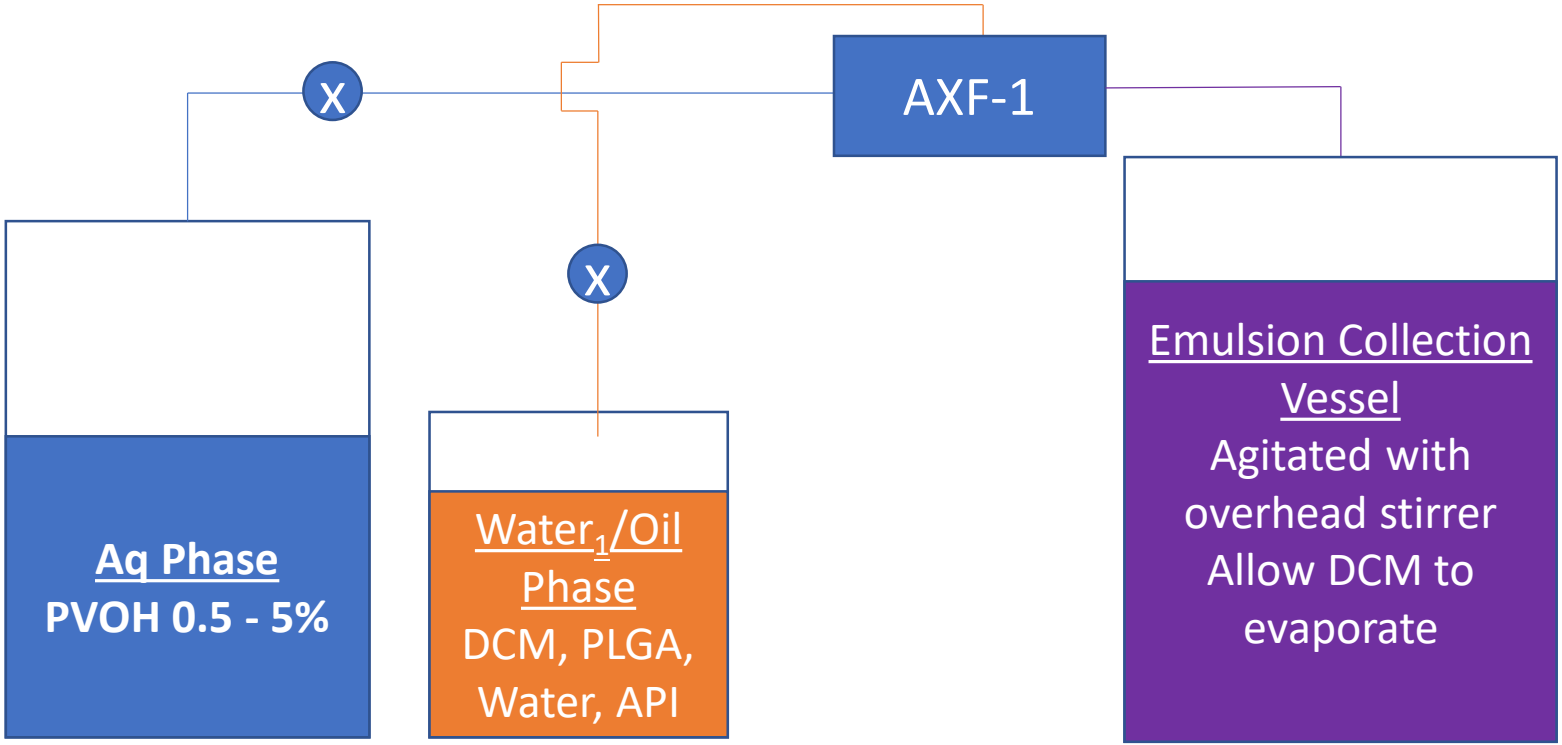
SEM of Polyamide capsules



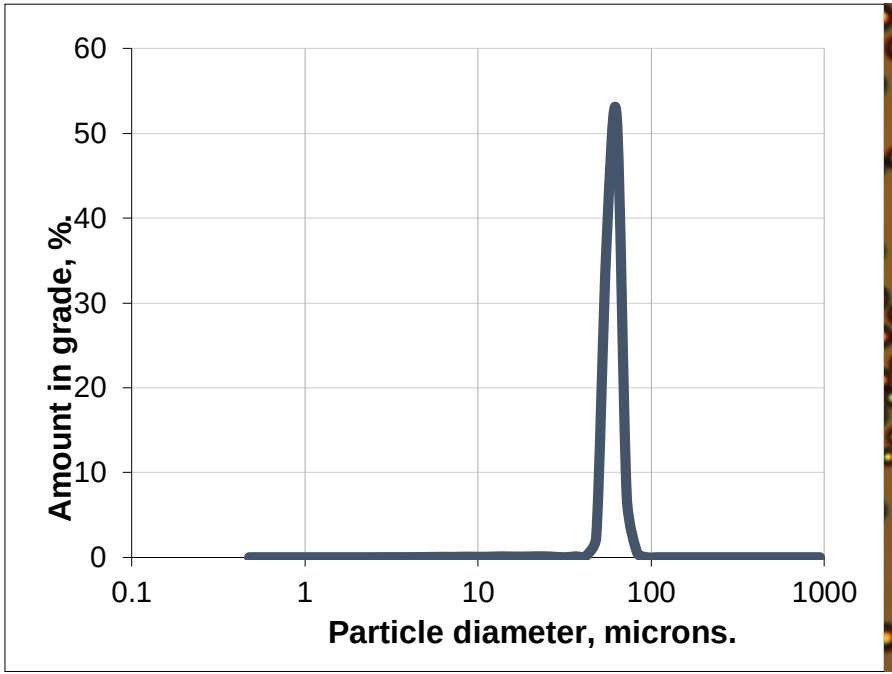
Applications in Encapsulation – Solvent Evaporation

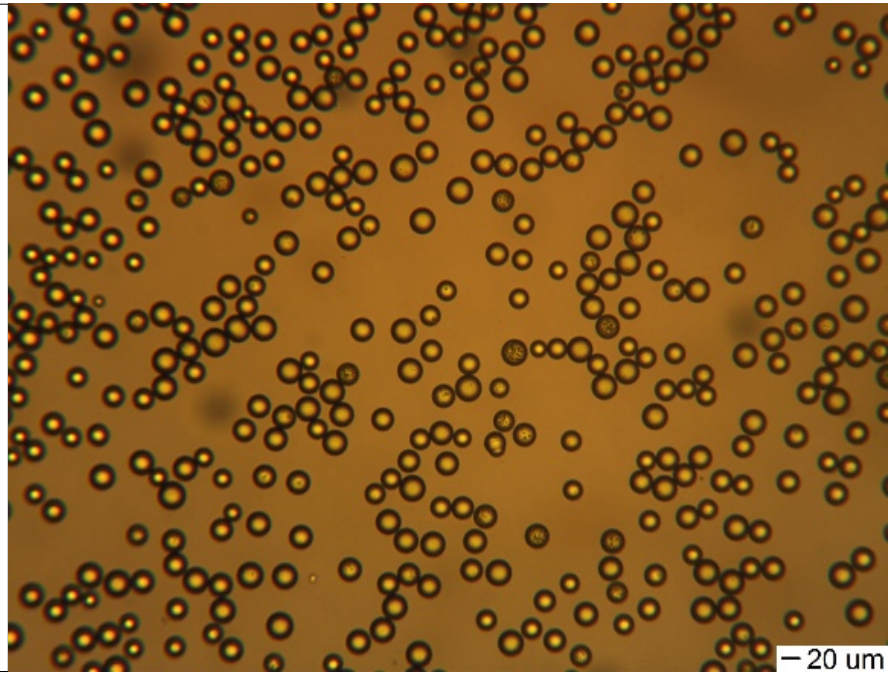


Double Emulsion PLGA capsules for drug delivery



Monodisperse PLGA particles

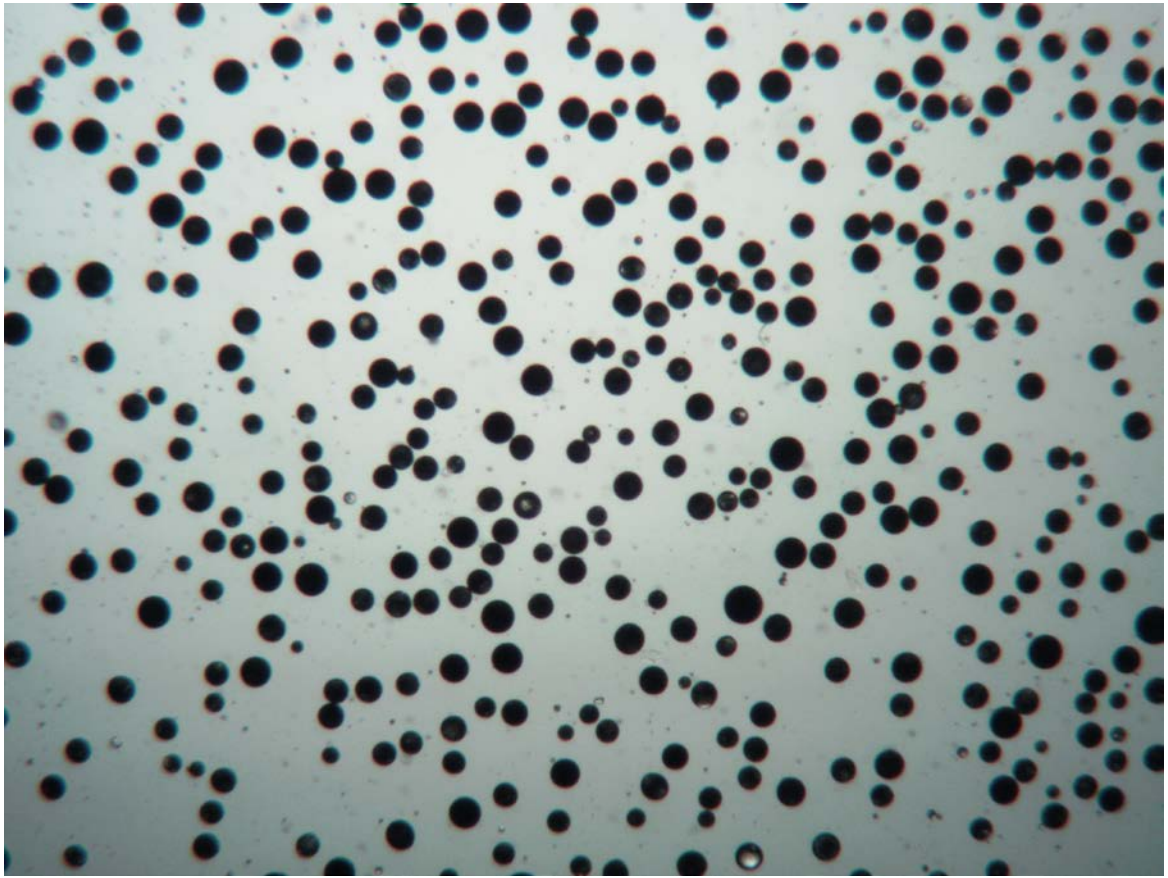




Volume Distribution	Diameter
D10	20.5 um
D50	24.2 um
D90	27.4 um

Statistical Analysis	
CV	11.3%

High quality double emulsions for sensitive APIs



Manufacturing capabilities

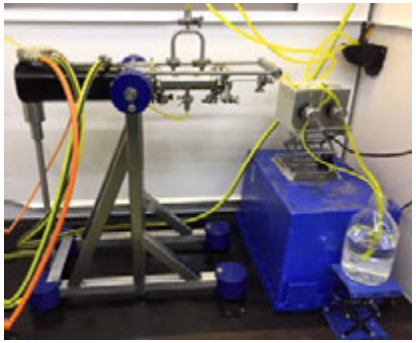
Scalability

Laboratory
100 ml / batch

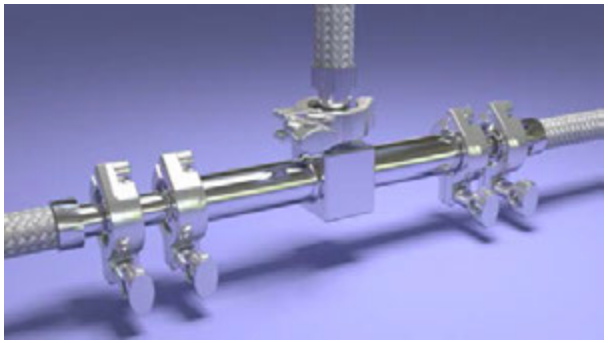
Development
Up to 10 kg / hour

Manufacturing
<1,500 tonnes / year

LDC-1



ATS-1

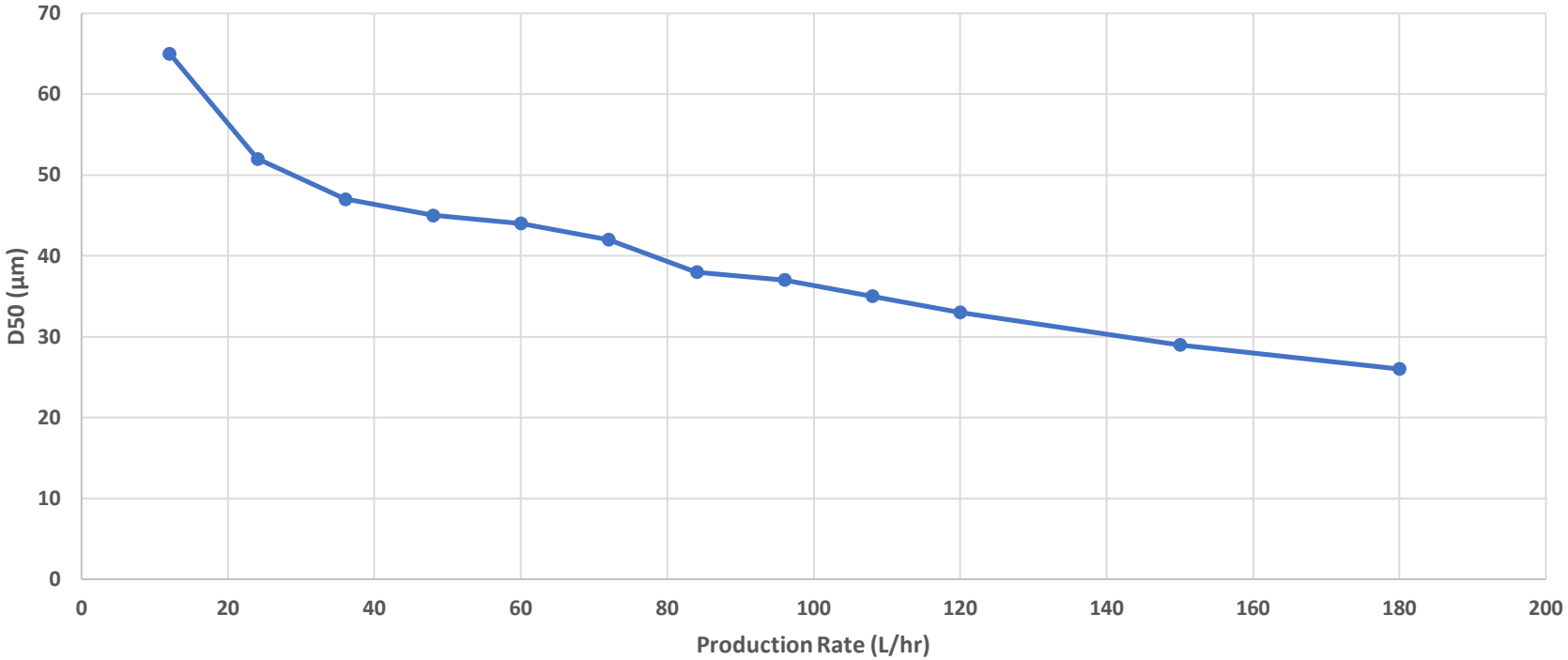


AXF-1

FDA / cGMP qualifying Development & Manufacturing equipment is available

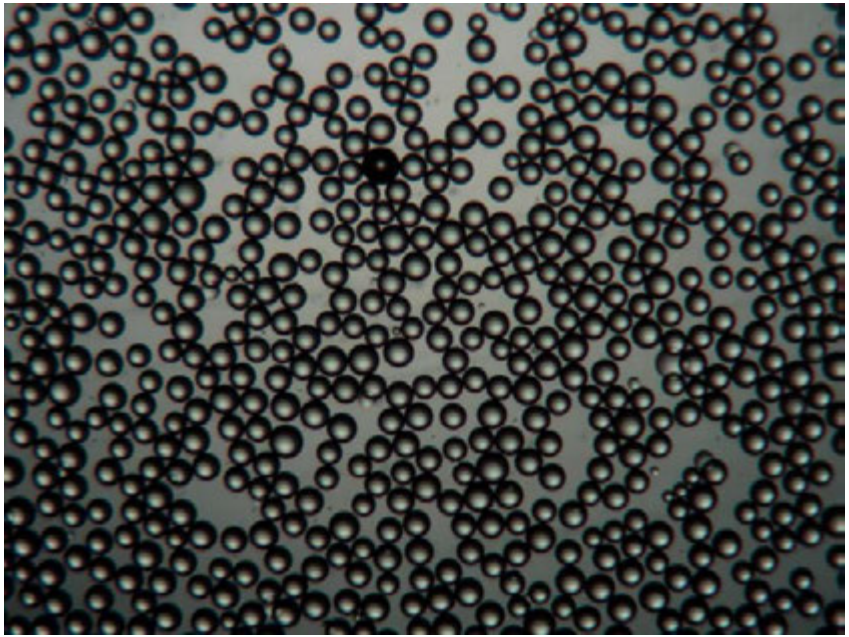
Production at a range of flow rates

Flow affects size – predictably

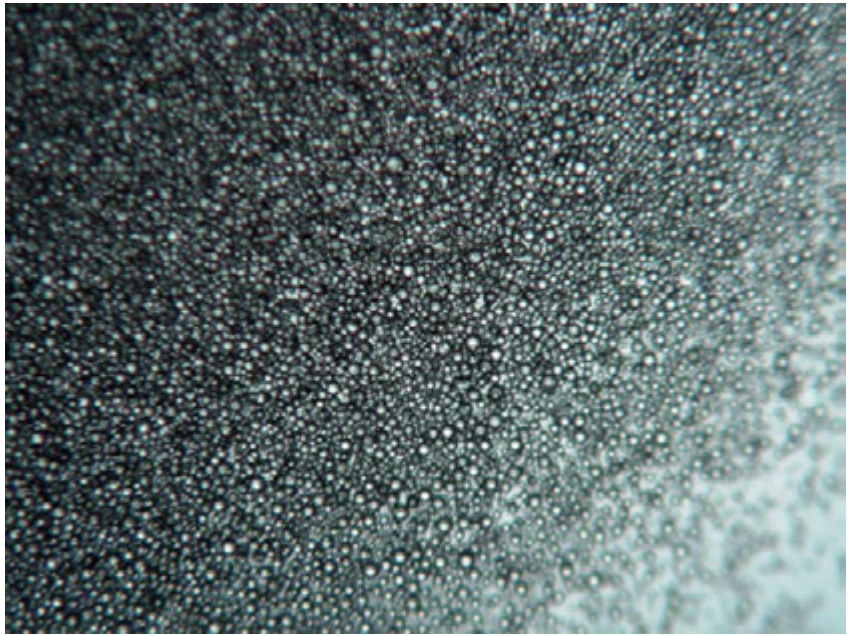


The effect of flow rate

12L/hr

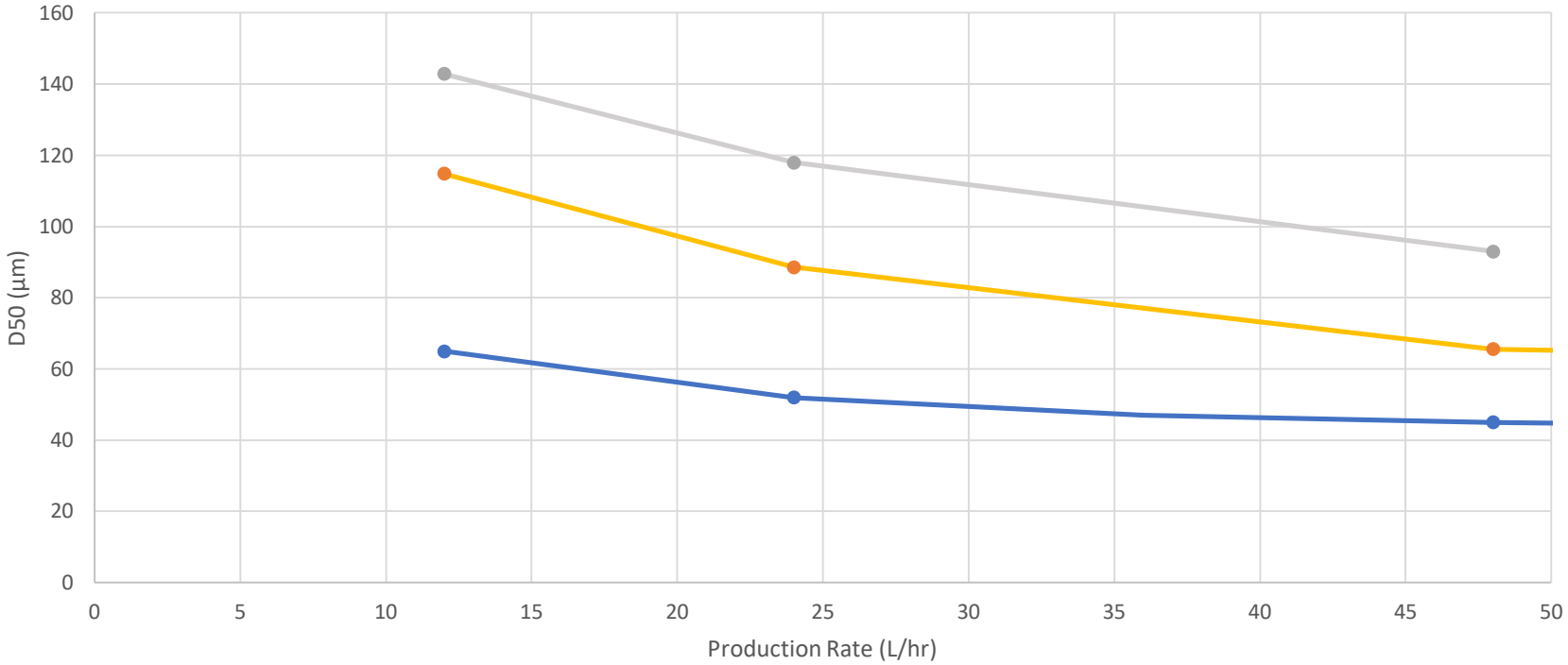


180L/hr



Capable of achieving different sizes at the same rates

Highly tunable – for particle size at chosen flow rate

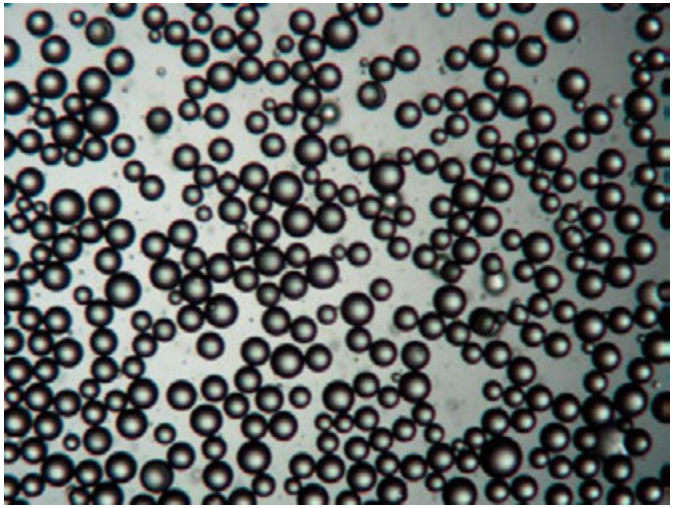


40% V/V Emulsions – Single Pass

Results obtained from the same membrane & equipment setup!

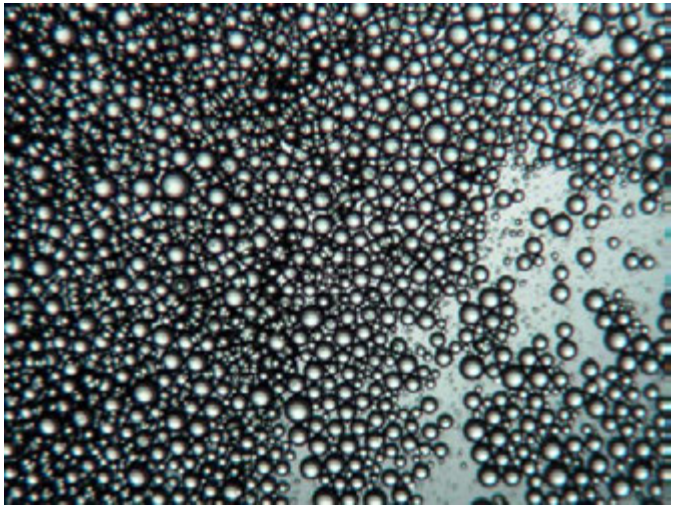
7.2L/hr Dispersed Phase
10.8L/hr Continuous Phase

18L/hr Product
D50: 80µm
Span: 0.3
CV:15%

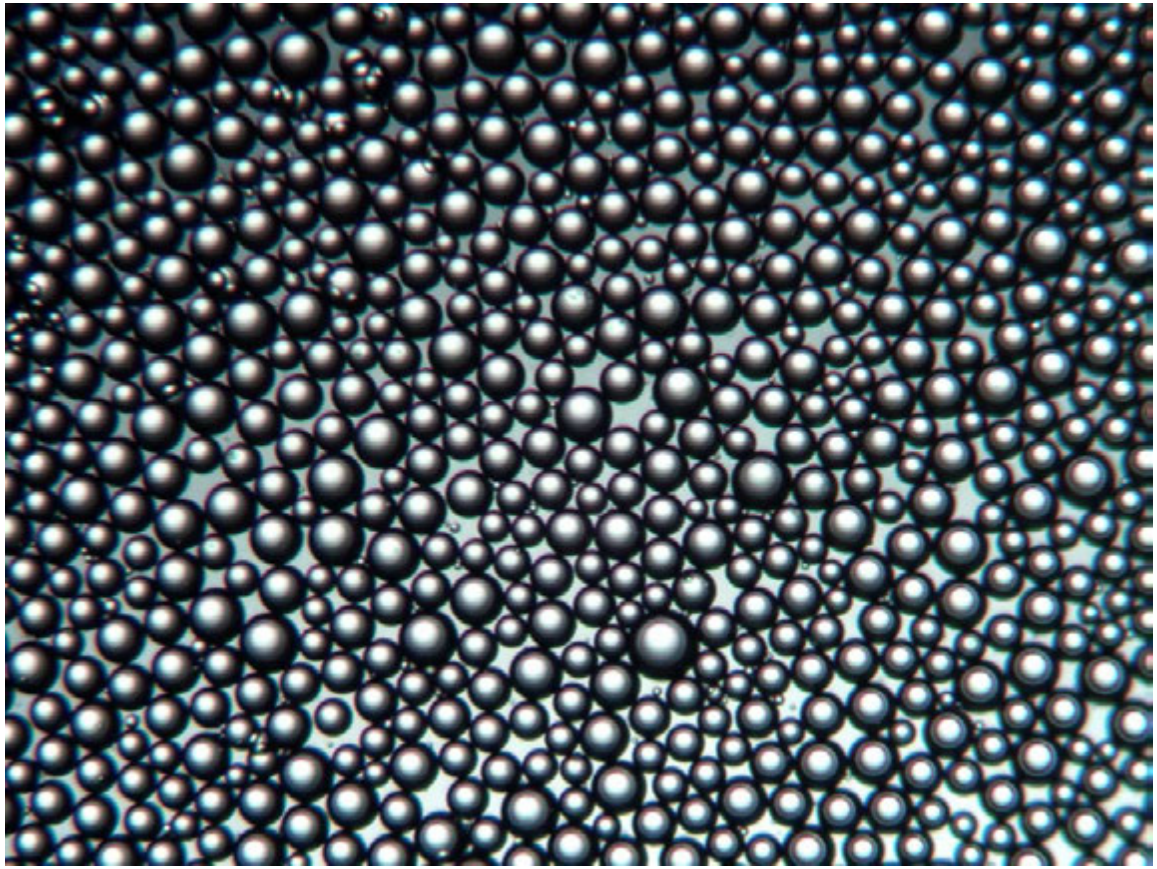


30L/hr Dispersed Phase
45L/hr Continuous Phase

75L/hr Product
D50: 55µm
Span: 0.6
CV: 25%



Initial Testing at 50% V/V Concentration……..



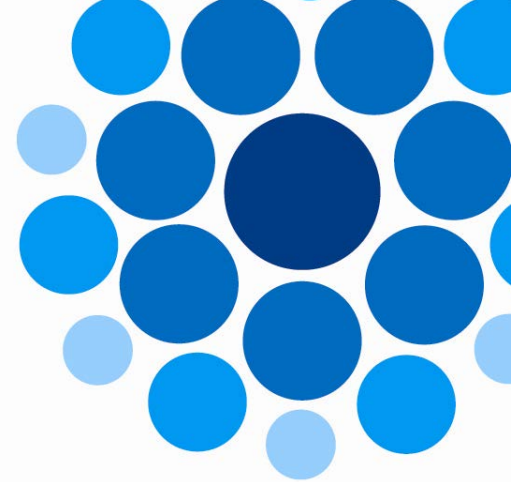
Scalability + +

Launching today

AXF-7

Manufacturing

<10,000 tonnes / year



Example benefits – Pharma API

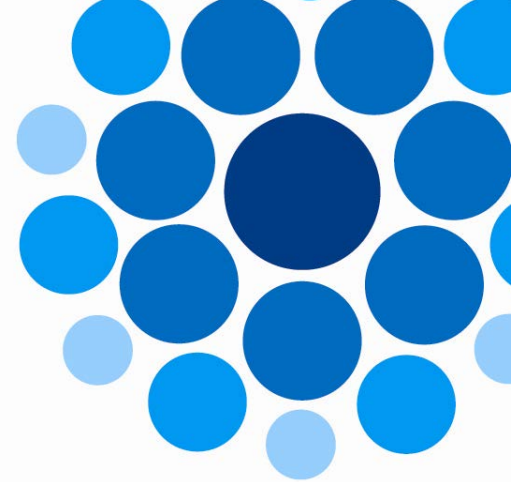
An example: Pharma market – Injectables

Selected parameter	Homogenisation
Waste	+30% (80% in 1 client)
Energy usage	40 KW
Biological integrity	<50%
Process	Labour intensive
Size distribution	Wide = needle bridging

An example: Pharma market – Injectables

Selected parameter	Homogenisation	Micropore's Technology
Waste	+30% (80% in 1 client)	**<5% (zero in most)**
Energy usage	40 KW	**2 KW**
Biological integrity	<50%	**>90%**
Process	Labour intensive	**Continuous: Start-up & walk away**
Size distribution	Wide = needle bridging	**Narrow = no needle bridging**

In Summary……..



Tunable size: 10 µm ⟶ 2 mm

Precision control = narrow PSD: Typical CV 10–20%

Multi-formulation capability

Lab ⟶ 10,000 tonnes/year ……. predictably

Membrane Emulsification has finally come of age……..

Thank you

Micropore Technologies

“Partners in Precision Particle Production”

Dai Hayward FRSC
CEO

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W: www.micropore.co.uk