

Producing Stable Nanoemulsions Utilizing Microfluidizer[®] Processors

TB-NE-1

Microfluidizer processors achieve unparalleled results producing stable emulsions with droplet sizes in the submicron to nanometer range for a variety of applications:

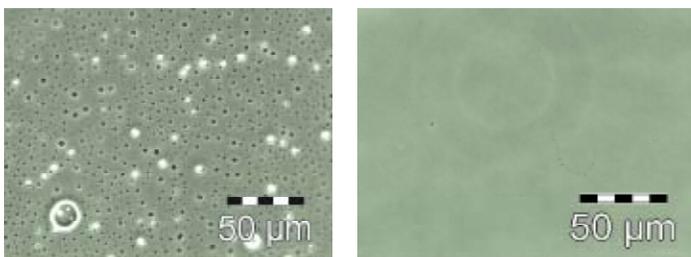
- Increased bioavailability
- Delivery of hydrophobic drugs
- Improved stability for new and existing products
- Simplified downstream processing (e.g. sterile filtration)
- Optimized formulation characteristics (e.g. rheology, optical, odor and taste masking properties)
- Nanoencapsulation for protection against oxidation

The Microfluidizer Processor Difference

- Produces smallest particle size and tightest distribution for stable results
- Highest shear force means less processing
- Reproducible results, batch to batch, day to day
- Scaleup guaranteed

Particle Size Reduction

Microfluidizer high shear fluid processors provide unrivaled uniform particle size reduction. Nanoemulsions with small particle sizes increase bioavailability and enable targeting (e.g. cancer drugs targeting and penetrating cancer cells.)

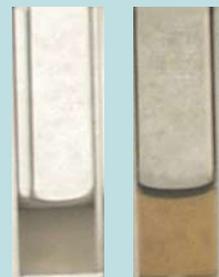


Before

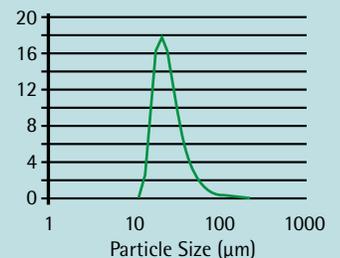
After



LV1 Microfluidizer processor for processing 1 - 6 ml of product



Formulation is translucent after processing.



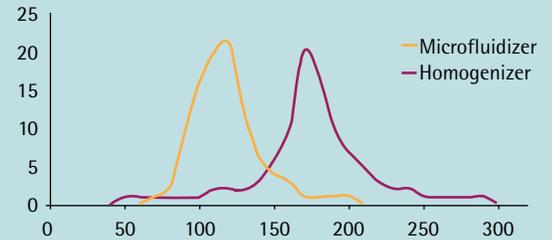
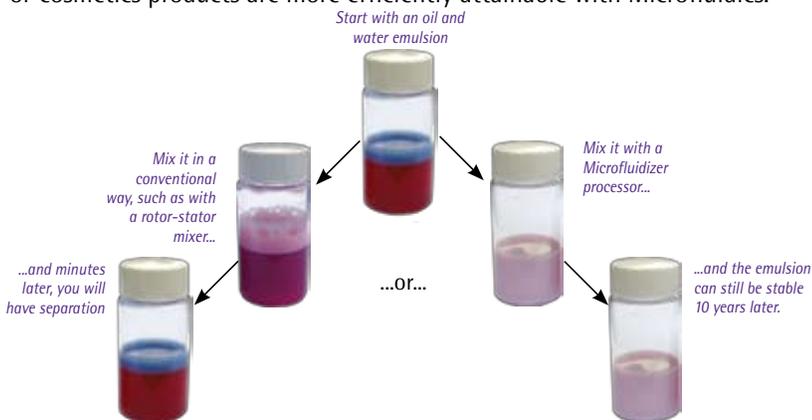
Median particle size (D50) AFTER: 45 nm. All particles are below 100 nm.

Sterile Filtration

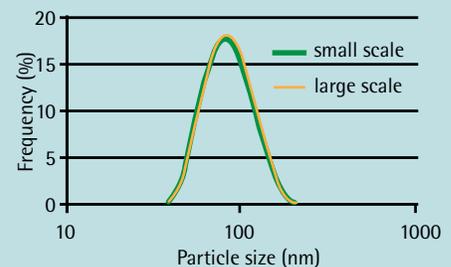
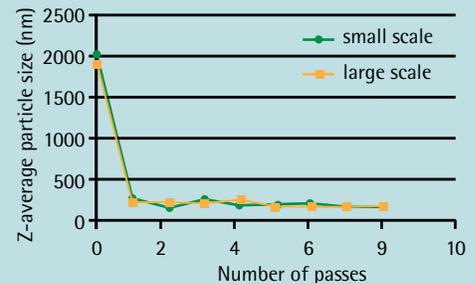
In addition to the inherent cost benefits of developing products with a prolonged shelf life, customers are usually able to reduce the processing time needed to reach particle size goals as compared to homogenizers, and typically can simplify downstream processing steps, as well. For pharmaceuticals, applications such as vaccine adjuvants are often nanoemulsions which need to be sterile filtered. Uniformly reducing particles to < 200 nm significantly reduces filter area required. Scaling up with Microfluidizer processors brings these cost benefits to production volumes.

Improved Stability and Scaleup Guaranteed

Instability and phase separation of emulsions and suspensions are the critical challenges faced by research and production teams, as most technologies cannot produce the particle size distribution necessary to reach product goals. Large particles, even in small amounts, destabilize emulsions. To overcome these issues, Microfluidizer processors use unique fixed-geometry interaction chambers to reduce particle sizes uniformly and to a level unmatched by other methods. This enables customers to optimize formulations for maximum stability with scaleup guaranteed and easy to achieve, even for those requiring FDA approval. Further, quality enhancements such as translucent appearances for food or cosmetics products are more efficiently attainable with Microfluidics.

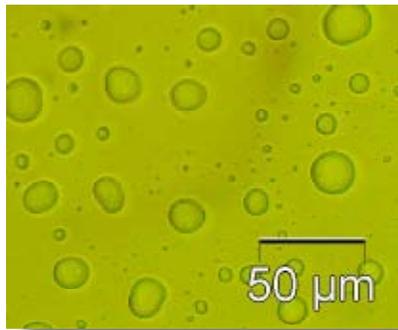


In this sterile filtration of a nanoemulsion for vaccine adjuvant, the emulsion processed by the Microfluidizer processor contain less than 1% of particles by volume > 200 nm. Emulsions processed with the homogenizer contained a significant amount of particles over 200 nm, therefore were difficult to filter sterilize.

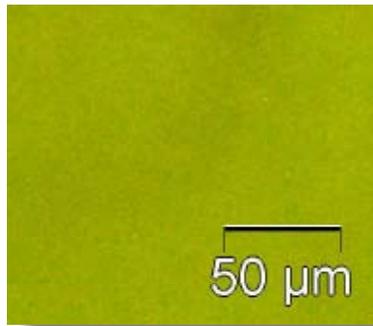


Oil/Water Emulsion – Fish Oil Encapsulation

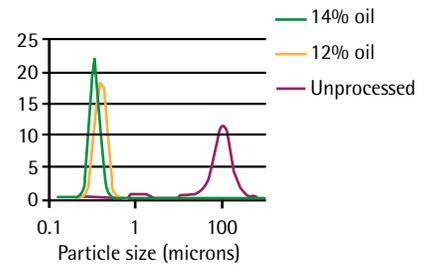
Odor and taste masking / oxidation protection of Omega 3 fatty acids



Before

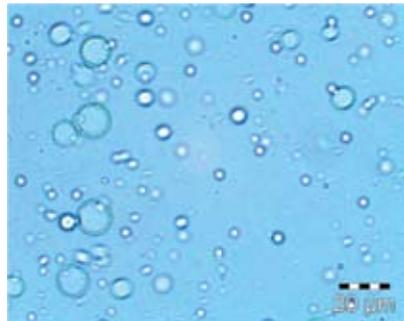


After



Fish oil contains Omega 3 fatty acid, which is an essential nutrient. By encapsulating the fish oil, the undesirable taste can be reduced substantially and the oil is protected from oxidation. Median particle size of 12% fish oil emulsion after processing: 0.163µm. Median particle size of 14% fish oil emulsion after processing: 0.119µm.

Oil/Water – Polymer Nanoemulsion



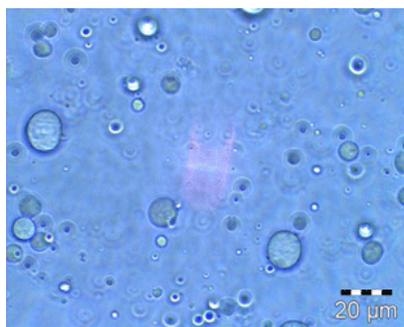
Before



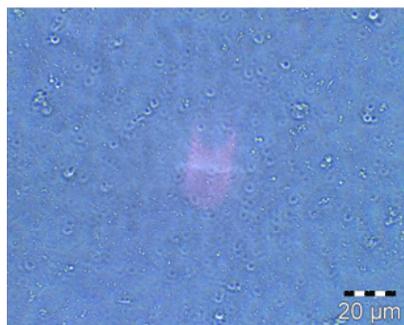
After

The drug is encapsulated in a polymer nanoparticle used to deliver hydrophilic drugs. Median particle size (D50) AFTER processing: 330 nm.

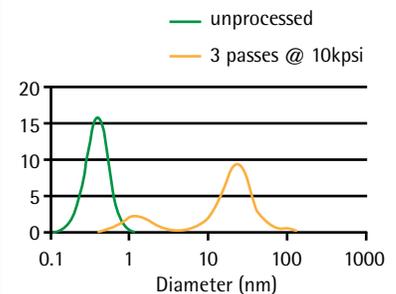
Palm Oil/Water – Wax Emulsion



Before



After

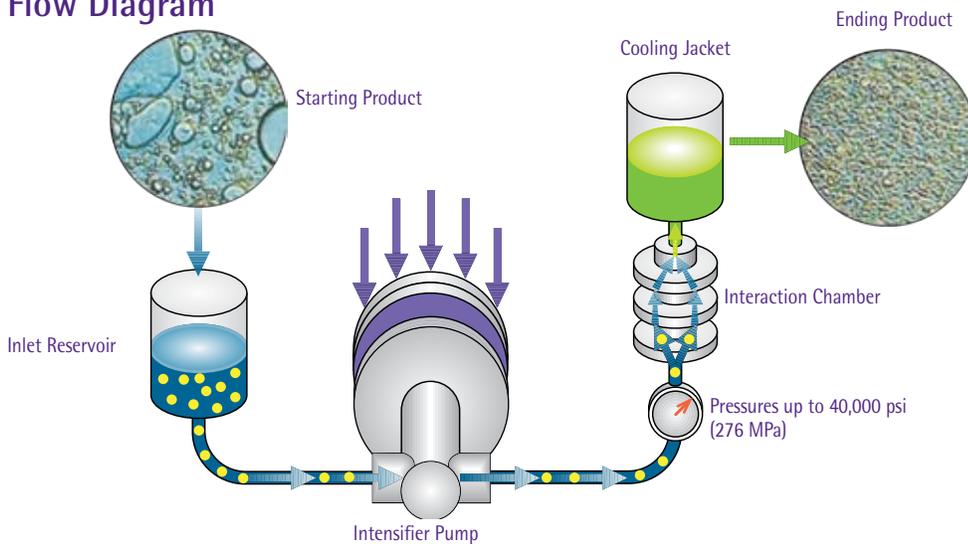


The material was processed above the melting temperature of the palm oil to ensure the palm oil was liquid. After processing, at 65°C, the emulsion was cooled down quickly below 20°C to solidify the palm oil particles. Unprocessed – Median particle size: 18.9 microns. After processing – Median particle size: 0.35 nm.

Microfluidizer Processors (Top Down)

Innovative Microfluidizer processor technology revolutionized fluids processing with its fixed-geometry (no moving parts) interaction chamber. Within the interaction chamber, highly-pressurized liquid product streams travel at high velocities through precisely defined microchannels producing high-shear forces. Unlike alternate processing technologies, our technology exposes 100% of your product to the same processing conditions, all the time, every time. As a result, your formulations will be consistent and reproducible, and they will scale readily from laboratory to production. The Microfluidizer processor's efficiency enables you to meet your processing objectives with fewer passes than alternatives.

Flow Diagram



Microfluidics Reaction Technology™ (Bottom Up)

Microfluidics Reaction Technology (MRT) utilizes a "bottom-up" proprietary approach whereby the particle is built up, molecule by molecule, in micro-seconds allowing not only for optimal and consistent sizing of the particles but also for the creation of smaller particle sizes not previously achievable. For customers interested in continuous manufacturing, MRT results in extreme phase purity of products.



Microfluidics Reaction Technology
-CR5-



Microfluidics

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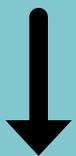
**Scaleup
Guaranteed**



from laboratory



through pilot



to production