

BaroShear™ K45

*For the Efficient Preparation of High Quality,
Water-Soluble Nanoemulsions of CBD Oil*

BaroShear K45 Processing System

The BaroShear K45 System utilizes our proprietary Ultra Shear Technology™ (UST™) platform to effectively produce high quality, water-soluble nanoemulsions of CBD Oil. The BaroShear K45 features a unique, custom-designed, highly efficient ultra-high pressure (UHP) generator subsystem to produce reproducible pressure levels up to 45,000 psi. The BaroShear K45 has a maximum throughput capacity of approximately 1 liter per hour. The platform is also well suited for processing small (20 mL minimum) to moderate volumes of high value CBD Oil to nanoemulsion levels with minimal loss during production.

Custom Designed Key Components

- **UHP Generator Subsystem.** Ideal for small volume processing.
- **Barolsolator.** Keeps product from entering pump, simplifies flow path, eliminates processing loss, and improves cleanliness.
- **NanoGap Valve.** Improves process uniformity and scalability by active flow throttling and integrated temperature control.
- **Temperature Control.** Built in temperature control before, during, and after shear disruption for maximum product quality and effectiveness.
- **Full Data Acquisition.** Easy to use touch screen control and GMP-ready record keeping system.



Ultra-Shear Technology Platform

The UST platform utilizes ultra-high pressure to create intense, instantaneous liquid shear under controlled conditions to generate ultrafine dispersions of nanoemulsified CBD Oil for infusion into beverages, cosmetics, nutraceuticals, pharmaceuticals, biotechnology and other products.

PBI's patented Barolsolator™ prevents CBD Oil from entering the pump of the custom-built, UHP generator subsystem. This results in a high level of cleanliness and pressure processing stability. The patented NanoGap™ valve then transforms the pressure energy into shear energy to produce nanoscale mixtures (i.e., nanoemulsions) of otherwise immiscible fluids (like CBD Oil in water), leading to longer product stability and greater solubility.

Nanoemulsions

Nanoemulsions have been shown to exhibit improved sensory experience, protect the visual and nutritional qualities of the material being processed, and to require lower amounts of added chemicals for preservation. For CBD Oil, nanoemulsions offer superior water solubility and increased bioavailability for improved absorption via oral or topical administration. UST processing, combined with temperature control, can also destroy spoilage organisms as well as potentially harmful pathogens, such as mold.

Key Features: BaroShear K45 vs. Conventional Homogenizers

Several key features differentiate the BaroShear K45 System from conventional homogenizers in the production of nanoemulsions.

- Homogenizers use fixed size flow channels or orifices that can lead to clogging. The BaroShear K45 System uses our proprietary NanoGap valve, with significantly smaller flow channels/orifices than conventional homogenizers, which results in more efficient physical fluid disruption. The NanoGap valve can work at very low flow rates and can reset to clear obstructions without disassembly.
- Homogenizer pumps can generate uneven flow resulting in broad particle distribution. The BaroShear K45 minimizes flow issues with its custom UHP generator subsystem, patented Barolsolator and NanoGap valve, and its exquisite temperature control to maintain constant fluid shear conditions.
- Conventional homogenizers are nearly impossible to scale up to pressures above 30,000 psi. The UST platform can be scaled to both higher pressures (up to 45,000 psi) and flow rates as needed due to the separation of the product handling section from our unique, custom designed UHP generator subsystem. The BaroShear K45 is ideally suited for small to moderate scale manufacturing processes of high value limited volume products, such as the processing of CBD Oil into nanoemulsions.

The proprietary features of the BaroShear K45 System provide a highly controlled manufacturing process that can yield a more uniform and higher quality product than other shearing devices and methods. The BaroShear K45 can be used in a variety of experimental and commercial manufacturing processes, including the formulation of high quality, long shelf stable nanoemulsions.

Applications of the BaroShear K45:

- Nanoemulsions
- Nanodispersions
- Microencapsulation
- Nanomaterials
- Deagglomeration
- Cell disruption

Key Features and Benefits:

- Scalability from discovery to manufacturing
- Easy to operate with simple controls
- Minimum volume: 20 mL
- Precise control of pressure range: 5,000 to 45,000 psi
- Multi-point temperature monitoring
- Temperature control for processing of thermally sensitive materials
- 21 CFR Part 11 compliant
- Secure automated batch records and audit trail
- On-site validation support including IQ/OQ, material certifications and calibrations
- On site installation, operation and maintenance training
- Clean-In-Place (CIP)-compatible flow path
- Easy to maintain with most maintenance points easily accessed

Target Specifications:

Maximum Operating Pressure	45,000 psi (3100 bar)
Maximum Product Flow Rate	5ml/sec at maximum target pressure
Maximum Product Viscosity	<50cP (at the processing temperature)
Feed Temperature Max.	4-75°C (40-165°F)
Temperature Control and logging – 4 points	Feed, Isolator chamber, UST Valve, Product Outlet
Holdup (Dead) Volume	<5 ml (excluding customer provided heat exchanger)
Electrical Requirement	230V (5 HP)
Product Outlet Heat Exchanger Cooling	Via customer external Chiller/Cooling water supply
Minimum Sample Size	20 ml
Dimensions H x W x D	63" H X 49" W X 43" D (est.)
Weight	480lbs (est.)

UST Patents and (selected) Patent Applications

Systems for High Pressure, High Shear Processing of Fluids

- Inventor: Ting, Edmund, Y.
- Filing Date: March 28, 2015
- Patent Number: ZL 201620243518.2
- Country: China

Ultrahigh Pressure Compact Valve with Throttling Capability

- Inventors: Ting, EY; Lazarev, Alexander; and Ma, Jun
- Filing Date: September 11, 2015
- Patent Number: ZL 201621148183.2ds
- Country: China

System of High Pressure, High Shear Processing of Fluids

- Inventors: Ting, Edmund, Y.
- Filing Date: March 28, 2016
- Patent Application Number: 15/758975
- Country: US

Ultrahigh Pressure Compact Valve with Throttling Capability

- Inventors: Ting, EY; Lazarev, Alexander; and Ma, Jun
- Filing Date: March 28, 2016
- Patent Application Number: 15/562146
- Country: US

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