Microfluidics™

Superior Knowledge | Superior Results



M815

Microfluidizer™

Pharma Basic Pilot Scale

Processor Series

M815 Microfluidizer™ Pharma Basic Pilot Scale Processor Series

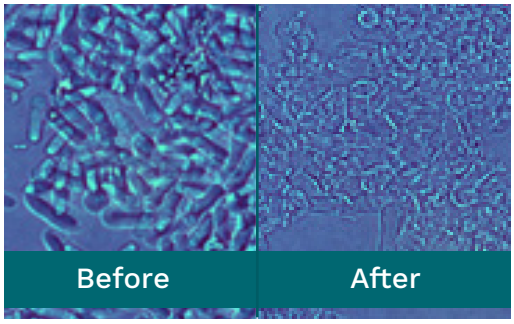
For Processing Clinical and Production cGMP Batches

Microfluidizer™ technology efficiently converts fluid pressure into shear forces, leading industry performance standards in high pressure processing.

A unique solution to maintaining consistent process pressure ensures 100% of your material gets exactly the same treatment. Whether you are working with small-scale lab batches or production volumes, the Microfluidizer processor is unmatched in submicron particle/droplet size reduction, cell disruption, product yield, and guaranteed process scale up.

Microfluidizer™

High efficiency cell disruption with minimal protein denaturation



Recommended For:

Non-sterile processing of:

- Cell Disruption
- Nano-emulsions (with/without API)
- Nano-dispersions
- Microencapsulation
- Fine Particle Deagglomeration

Unique Benefits of the M815

- Produces product flow rates up to 1200 mL/min at 689 - 2068 bar (10,000 - 30,000 psi)
- Has small batch capability; handles a minimum sample size of 1.5L
- Features a low product hold-up volume (800 mL)
- Is CIP process capable
- Integral feed pump and heat exchanger
- Lockable casters, standard door width for easy mobility
- Meets CE compliance standards
- Standard with 7” touchscreen HMI
- Allows monitoring of key process parameters
- Facilitates non-destructive processing of heat-sensitive materials
- Assures batch-to-batch process repeatability
- Features sanitary-grade and BPE-compliant product paths, instruments and valves
- Offers process pressure and temperature monitoring with local display and signal transfer to customer’s data acquisition system
- Includes a complete document turnover package for validation support, including IQ/OQ, material certifications and calibrations
- Factory Acceptance Testing (FAT)
- Includes on-site start-up assistance, operator and maintenance training, SAT and IQ/OQ execution by our technical staff
- Enhanced version available with 15” industrial personal computer (IPC) that is able to validate under 21 CFR to cGMP with purchase of data logging option

M815 Microfluidizer™ Pharma Basic Pilot Scale Processor Series

Operating Principle

Like all Microfluidizer™ processors, the M815 utilizes the fixed-geometry Interaction Chamber™ and constant pressure pumping system. This technology allows users to achieve smaller particle sizes — with more uniform distribution and scale-up guaranteed (both from lab scale and to larger scale units) — than can be obtained with other methods.

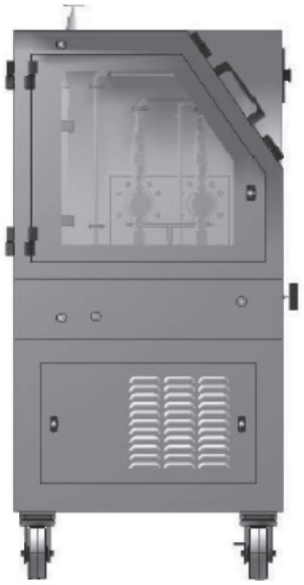
The M815 models were designed to bridge the gap between the lab scale (M110EH) and production scale (M700 Series) models, and they are ideal for manufacturing batches in the range of 100L-300L, which are necessary for PHII and PHIII clinical trials.

Standard Features

- Product feed pump, pharmaceutical grade with pressure gauge and purge valve
- Diamond Interaction Chamber
- Ceramic Auxiliary Processing Module™ (APM™)
- Ceramic (zirconia) plunger and seal quench for extended seal life
- Pharma grade heat exchanger
- Stainless steel enclosure
- Gauges for measuring hydraulic drive pressure, hydraulic oil level and temperature
- Self-contained unit, mounted on locking casters for portability, standard door width
- Feed temperature range 2˚C – 75˚C (35˚F – 165˚F)
- TEFC (totally enclosed fan-cooled) motor - starter optional
- Sanitary flush diaphragm pressure transducer with digital readout
- Class IV seals and gaskets certified
- 2 RTD temperature sensors

Options

- Motor starter
- Additional RTD temperature sensor
- Steam-In-Place
- Heat exchange temperature control



Specifications

Pressure Range	Up to 30,000 psi (2068 bar)
Flowrate Range	1.0-1.2 L/min
Dimensions	59”L x 34”W x 79”H (150cm x 86cm x 201cm)
Weight	1950 lbs (886 kg) With Oil 1800 lbs (818 kg) Without Oil

Note: Some options may change overall dimensions and weight of the machine.



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