Microfluidics™

Superior Knowledge | Superior Results

M110EH

Pharma Basic

Microfluidizer™ Processor

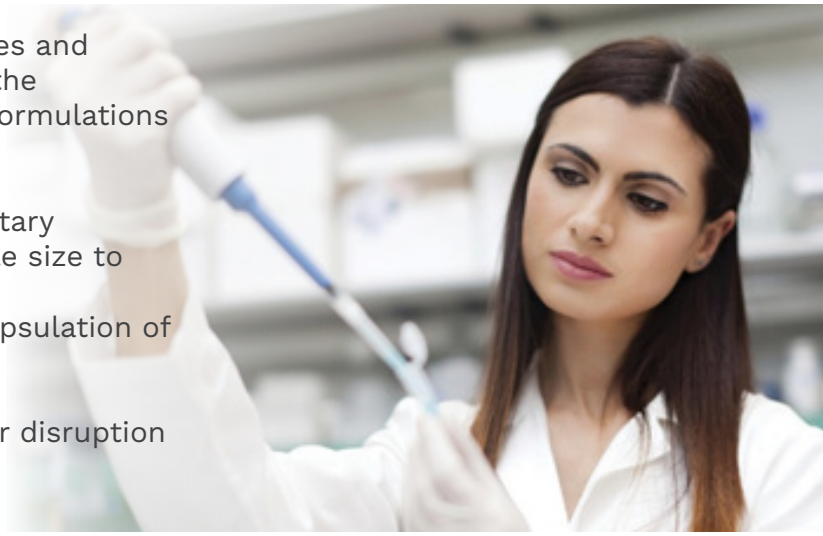
IDEX
Material Processing Technologies

M110EH Pharma Basic Microfluidizer™ Processor

Since 1984, Microfluidics has provided life sciences and formulation scientists with critical tools used in the development and production of pharmaceutical formulations and recombinant technologies.

High shear fluid processing, Microfluidics' proprietary technology, uniformly reduces droplet and particle size to enable the production of stable nano-emulsions, nano-suspensions, liposomes and the nano-encapsulation of actives.

In addition, it offers the most efficient method for disruption of yeast, E. coli, plant and mammalian cells.



Microfluidizer™

Recommended For:

- Nano-emulsions (with and without API)
- Nano-dispersions
- Microencapsulation
- Cell disruption
- Fine Particle Deagglomeration

Unique Benefits

- Validatable under 21 CFR to cGMP
- Easy to operate with simple manual controls
- Easy to maintain with most maintenance points easily accessible
- Pressure and temperature monitoring
- CIP process capable
- Thermally sensitive materials processed safely
- Cost effective production capability
- Batch to batch process reproducibility

Standard Features

- Diamond Interaction Chamber™ for flow rates up to 320 ml/min @ 2068 bar (30,000 psi) or 450 ml/min @ 1724 bar (25,000 psi)
- Ceramic Auxiliary Processing Module™ (APM™)
- Ceramic (zirconia) plunger and seal quench for extended seal life
- Stainless steel enclosure
- Gauges for measuring hydraulic drive pressure, and hydraulic oil level and temperature
- Self-contained unit, mounted on locking casters for portability
- Feed temperature range 16ºC to 75°C (35ºF to 165°F)
- TEFC (totally enclosed fan cooled) motor, starter, controls and power cord
- Sanitary flush diaphragm pressure transducer with digital readout
- Solvent seal quench system

M110EH Pharma Basic Microfluidizer™ Processor

M110EH Pharma Basic Microfluidizer Processor Includes:

- Features and documentation to enable validation under 21 CFR for cGMP, including;
  - Turnover documentation package for validation, material certifications and calibrations
  - IQ/OQ documentation
  - Startup assistance, maintenance, and operation training
  - Product wetted surfaces finished to 20 Ra (0.5µm) electropolished where possible, all surfaces passivated
- Manual controls
- Stainless steel construction CE compliant
- Motor starter
- Factory Acceptance Testing (FAT)
- Site Acceptance Testing (SAT)
- Installation Qualification / Operational Qualification (IQ/OQ) Execution
- Product heat exchanger - Pharma grade, with manual CIP and relief valve
- Sanitary flush diaphragm pressure transducer with readout and analog signal re-transmission
- Dual product temperature sensors and read outs (two thermocouples and digital read outs with signal retransmission mounted in a black anodized enclosure)

Key Features

- Up to 450 ml/min flow rate at 1724 bar (25,000 psi)
- 320 ml/min product flow rate at 2068 bar (30,000 psi)
- Small batch capable (minimum 200 ml)*
- Low product holdup volume (180 ml)*
- Motor starter and process interlocks
- Process pressure and temperature monitoring with local display and signal transfer to customer's data acquisition system
- Manual Clean In Place using customer's CIP system pump or optional feed pump
- All product paths are sanitary grade and BPE compliant
- All instruments and valves are sanitary grade, BPE compliant
- Complete document turn over package for validation support including IQ/OQ, material certifications and calibrations
- Factory Acceptance Testing (FAT)
- Onsite start-up assistance, operator and maintenance training
- SAT and IQ/OQ execution by our technical staff

Options

- Product feed pump, pharmaceutical grade with pressure gauge and purge valve
- 2 liter reservoir, pharmaceutical grade
- Filtered hydraulic oil
- On-board air compressor for air switch activation

M110EH Pharma Basic Microfluidizer™ Processor

Pressure Range	up to 2068 bar (30,000 psi)
Flow Rate	up to 320 ml/min at 2068 bar (30,000 psi) up to 450 ml/min at 1724 bar (25,000 psi)
Feed Temperature Max	75°C (165°F)
Holdup Volume	180 ml*
Electrical	3 phase 60 Hz service, 208/230/460V, 3.7 kw (5 hp) [50 Hz European standard available]
Compressed Air	0.03 m3/min @ 3.4 bar (1 SCFM @ 50 psi) with -37 to -17°C (-35° to 0°F) maximum dewpoint
Hydraulic Oil Heat Exchanger Cooling Water	9.5 lpm minimum @ 29°C maximum (2.5 gpm @ 85°F)
Product Outlet Heat Exchanger Cooling Water	18.9 lpm @ 0°C (5 gpm @ 32°F)
Minimum Sample Size	200 ml*
Dimensions L x W x H	84 x 94 x 180 cm (33” x 37” x 71”)
Weight	205 kg (450 lbs.)

Discovery to Commercialization

As a result of recent advances in high throughput screening and drug discovery, many new chemical compounds have been identified as possible drug candidates. Unfortunately, many of these compounds show poor water solubility and often are only marginally soluble in oil-based solvents.

The ultra high shear force developed by Microfluidizer processors solves this problem by reducing the particle size of active pharmaceutical ingredients to therapeutically relevant sizes that enables the production of drug products with improved bioavailability and stability.

Cell Disruption for Biotechnology

From the gentle disruption of cultured cells for virus isolation to the challenging disruption of yeast and other fungi, Microfluidics offers technologies to meet the variable and demanding needs for cell membrane disruption. This technology provides exacting process control for highly reproducible and efficient cell breakage while keeping temperatures under precise control to prevent denaturing.

Getting To Full Production

Results obtained on all laboratory units will scale up easily and in a linear manner to production volumes when the same operating conditions are employed.

Our processors are available with Steam In Place for aseptic processing, Ultra Clean In Place eliminating the need for disassembly and clean out of place (COP). Data recording and validation support documentation including IQ/ OQ is offered to ensure your ability to comply with 21CFR part 11 guidelines.

*depending on heat exchanger option

Microfluidics™

Microfluidics International Corporation
90 Glacier Drive, Suite 1000,
Westwood, MA 02090, USA

Tel: 617-969-5452 • 800-370-5452
Fax: 617-965-1213

Email: mixinginfo@idexcorp.com
Web: www.microfluidics-mpt.com

Industry Leading Insights & News:
https://www.microfluidics-mpt.com/blog

IDEX
Material Processing Technologies