Microfluidics™

Superior Knowledge | Superior Results

# M110EH

## Pharma Aseptic

## Microfluidizer™ Processor

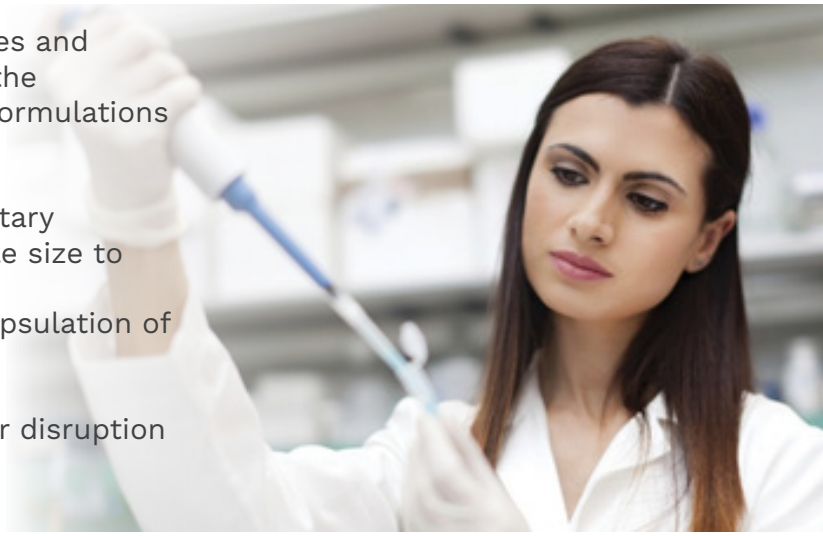
IDEX Material Processing Technologies

# M110EH Pharma Aseptic 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 sterility that will pass the Sterile Fill Test
- Easy to operate with automatic controls
- Easy to maintain with most maintenance points easily accessed
- Highly secure batch records, 21 CFR Part 11 compliant
- CIP process with no equipment takedown
- Thermally-sensitive materials processed safely
- Cost-effective production capability
- Batch-to-batch process reproducibility

## Standard Features

- Diamond interaction chamber for flow rates up to 330 mL/min @ 2068 bar (30,000 psi) or 450 mL/min @ 1724 bar (25,000 psi), product and chamber
- Ceramic Auxiliary Processing Module (APM)
- Ceramic (zirconia) plunger and seal quench for extended seal life Stainless steel enclosure
- Class VI seals and gaskets certified
- 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
- Product feed pump, pharmaceutical grade with pressure transducer and purge valve

# M110EH Pharma Aseptic Microfluidizer™ Processor

## M110EH Pharma Aseptic Microfluidizer Processor Includes:

- Steam-In-Place (SIP) with multiple RTDs to assure complete sterilization
- Ultra-Clean-In-Place (UCIP)
- Process monitor and HMI panel, Siemens Series PLC with 19” IPC; 21 CFR part 11 compliant for electronic signatures and record keeping
- 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
- Automatic controls CE compliant
- 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
- Product coolant temperature control, automatic
- Dual product temperature sensing by RTDs

### Options

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

### Key Features

- Up to 450 mL/min flow rate at 1,724 bar (25,000 psi)
- 330 mL/min product flow rate at 2,068 bar (30,000 psi)
- Small batch capable: 1L
- Low product holdup volume: 810 mL
- Motor starter and process interlocks
- Ultra-Clean-In-Place (UCIP) using feed pump
- All product paths are sanitary grade and BPE compliant
- All instruments and valves are sanitary grade, BPE compliant
- On-board data acquisition for complete batch record audit trail
- Multi-point temperature sensing for assured SIP process
- PID control of process chilled water for product temperature management
- Factory Acceptance Testing (FAT)
- Complete document turn over package for validation support including IQ/OQ, material certifications and calibrations
- On site start-up assistance, operator and maintenance training, SAT and IQ/OQ execution by our technical staff

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|---|---|
| Pressure Range | up to 2068 bar (30,000 psi) |
| Flow Rate | up to 320 ml/min at 2068 bar (30,000 psi)<br>up to 450 ml/min at 1724 bar (25,000 psi) |
| Feed Temperature Max | 75°C (165°F) |
| Holdup Volume | 810 mL |
| Electrical | 3 phase 60 Hz service, 208/230/460V,<br>3.7kW (5hp) [50 Hz European standard available]<br>1 Phase, 110V/220V//50Hz/60Hz//2.5kW |
| Compressed Air | .03 nm/min @ 3.4 bar (1 SCFM @ 50 psi) with -18 to 37°C (-35° to 0°F ) maximum dewpoint<br>0.4 m3/min @ 7 bar (14 SCFM @ 100 psi) and -37°C to -18°C (-35°F to 0°) dew point |
| 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 | 1L |
| Dimensions L x W x H | 196 x 168 x 94 cm (77” x 66” x 37”) |
| Weight | 410 kg (900 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.

Microfluidics™

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