

M-110EH-30 Aseptic BioPharmaceutical Microfluidizer® Processor

TB-BPEHA-2

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: 200 ml
- Low product holdup volume: 180 ml
- Motor starter and process interlocks
- Ultra Clean In Place (UCIP) 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
- On board data acquisition for complete batch record audit trail
- Multi-point temperature sensing for assured SIP process
- Flow totalizer to record product and CIP volume
- 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



M-110EH-30 Aseptic BioPharm Microfluidizer processor for sterile processing of clinical and production batches

Recommended for sterile processing

- Nanoemulsions (with and without API)
- Nanodispersions
- Microencapsulation
- Deagglomeration
- Cell disruption

Key benefits

- Validatable sterility that will pass the Sterile Fill Test
- Easy to operate with simple manual 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 assured

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.

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 ultrahigh 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 you're ability to comply with 21CFR part 11 guidelines.



30 Ossipee Road
 Newton, MA 02464 USA
 Tel: 1-800-370-5452 or: 617-969-5452
 Fax: 617-965-1213
 e-mail: mixinginfo@idexcorp.com
www.microfluidicscorp.com

M-110EH Aseptic Specifications

| | |
|---|---|
| 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 |
| Utility Requirements: | |
| • Electrical | 3 phase 60 Hz service, 208/230/460V, 3.7 kw (5 hp) [50 Hz European standard available] |
| • Compressed Air | .03 nm/min @ 3.4 bar (1 SCFM @ 50 psi) with -18 to 37°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 H x W x D | 150 x 205 x 71 cm (59" x 80" x 28") |
| Weight | 410 kg (900 lbs.) |

Aseptic BioPharm Microfluidizer Processor Includes

- Steam In Place (SIP) with multiple RTDs to assure complete sterilization
- Ultra-Clean-In-Place (UCIP)
- Process monitor and HMI panel, Yokogawa DX200P; 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
- Manual 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

M-110EH-30 Aseptic BioPharm 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)
- 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 16°C to 75°C (35°F to 165°F)
- TEFC (totally enclosed fan cooled) motor, starter, controls and power cord
- Sanitary flush diaphragm pressure transducer
- Flow totalizer input to process monitor and HMI panel

M-110EH-30 Aseptic BioPharm Available Options

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

