M-7125, M-7250 Enhanced BioPharmaceutical Microfluidizer Processor

TB-BP7.E-1

Key Features:

- Complete package unit including motor starter panel and process interlocks
- Up to 15 LPM (4.0 GPM) flow rates at 690bar (10,000psi) process
- 7.5 LPM product flow (2.0 GPM) at 1,380bar (20,000psi)
- 5.1 LPM product flow (1.3 GPM) at 2,068bar (30,000psi)
- Small batch capable (minimum 12L)
- Low product holdup volume (<1L)
- On board data acquisition for complete batch record audit trail
- Ultra Clean In Place using supplied feed pump or your CIP system pump
- On board flow meter to measure product and CIP flow rates
- All product paths are sanitary grade and BPE compliant
- All instruments and valves are sanitary grade, BPE compliant
- PID control of process chilled water for product temperature management
- Complete document turn over package for validation support
- Start-up assistance including: Training, SAT and IQ/OQ execution by our technical staff

M-7125 and M-7250 Enhanced BioPharmaceutical Package Provides Superior Results For Pilot and Production Environments

Recommended for non-sterile processing

- Nano-emulsions (with and without API)
- Nano-dispersions
- Microencapsulation
- Deagglomeration
- Cell Disruption

Key benefits:

- Guaranteed scale up from lab and pilot Microfluidizer® processors
- 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
- More efficient processing, usually requiring less passes than other homogenizers
- Batch to batch process reproducibility assured

Microfluidics

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, 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 guidelines

Specifications

	M-7125	M-7250
Pressure Range	up to 10,000, 20,000 or 30,000 psi (689, 1379, or 2068 bar)	
Product Flow Rate*	up to 2.0 gpm (7.56 lpm)	up to 4.0 gpm (15.12 lpm)
Product Feed Temperature Range	14°F to 165°F (-10°C to 75°C)	
Power Requirement	25 HP (18.6 kw)	50 HP (37.3 kw)
Utility Requirements	• Cooling water for hydraulic oil heat exchanger • Cooling water for process fluid heat exchanger • Compressed air for feed pump and cycling control switches [90 psi (6.2 bar) @ 23 scfm (.065 m3/min) minimum 0°F to -35°F (-18°C to -37°C) dew point]	
Dimensions**	82.3" (209 cm) X 42" (107 cm) X 72.7" (185 cm)	
Weight**	1850 lbs (816 kg)	2400 (1089 kg)

*based on water **all weights and dimensions are approximate

Enhanced BioPharm Package Includes

- Validatable under 21 CFR for cGMP
- Turnover documentation package for validation
- Installation Qualification / Operational Qualification (IQ/OQ) documentation
- Installation Qualification / Operational Qualification (IQ/OQ) execution
- Startup and training
- Stainless steel construction
- Product wetted surfaces finish to 20 Ra (0.5µm) nominal, electropolished and passivated
- Manual controls
- Feed pump, pharmaceutical grade
- CE compliant
- Interaction chamber selected for your application
- Factory Acceptance Testing (FAT)
- Site Acceptance Testing (SAT)
- Product heat exchanger - Pharma grade
- Motor starter panel
- Ultra Clean In Place (UCIP)
- Product heat exchanger - Pharma grade with active product temperature control
- Mass flow meter - Pharma grade
- Data acquisition and recorder system, Yokogawa DX200P; 21 CFR Part 11 compliant for electronic signature and record keeping
- Proprietary high pressure diaphragm priming valve
- Process pressure and temperature sensing

Available Options

- Product inlet strainer
- Hydraulic oil
- Explosion proof (XP) compliant version available
- ATEX compliant version available

Microfluidics

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