M-7125, M-7250 Basic BioPharmaceutical Microfluidizer Processor

Key Features:

- Motor starter panel and process interlocks
- Up to 15 LPM (4.0 GPM) flow rates at 690bar (10,000psi)
- 7.5 LPM (2.0 GPM)product flow 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)
- Process pressure monitoring with signal transfer to customer's data acquisition system
- Optional product temperature monitoring with signal transfer to customer's data system
- Optional Ultra Clean In Place using supplied feed pump or customer's CIP system 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
- Start-up assistance including: Training and IQ/OQ
- Optional FAT, SAT and IQ/OQ execution by our technical staff

M-7125 and M-7250 Basic Biopharmaceutical Configuration Package for Economical Production of Clinical and Production Batches

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
- Validatable under 21 CFR to cGMP
- Easy to operate with simple manual controls
- Easy to maintain with most maintenance points easily accessed
- Key process parameter monitoring
- CIP process with no equipment takedown required
- Thermally sensitive materials processed safely
- Cost effective production capabilities
- 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, Ultra Clean In Place eliminating the need for disassembly and clean out of pla ce (COP). Data recording and validation support documentation including IQ/OQ is offered to ensure your 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**	83"L x 31"W x 61"H (211cm x 79cm x 155cm)	
Weight with oil**	1,800 lbs. (816 kg)	2,400 lbs (1089 kg)

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

Basic BioPharm Package Includes:

- Features and documentation to enable validation under 21 CFR for cGMP, including;
  - Turnover documentation package for validation
  - IQ/OQ documentation
  - Startup and training
  - Product wetted surfaces finished to 20 Ra (0.5µm) nominal, electropolished and passivated
  - Feed pump, pharmaceutical grade
- Manual controls
- Stainless steel construction
- CE compliance
- Interaction chamber selected for your application
- Proprietary high pressure diaphragm priming valve

Available Options:

- Factory Acceptance Testing (FAT)
- Site Acceptance Testing (SAT)
- Installation Qualification / Operational Qualification (IQ/OQ) Execution
- Product heat exchanger - Pharma grade
- Motor starter panel
- Explosion proof (XP) compliant version available
- ATEX compliant version available
- Product inlet strainer
- Dual product temperature sensing read out (two thermocouples with two digital read outs in a black annodized enclosure)

Microfluidics

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