M-7125, M-7250 Aseptic BioPharmaceutical Microfluidizer® Processor

TB-BP7.A-1

Key features

- Up to 15 lpm (4.0 gpm) flow rates at 690 bar (10,000 psi)
- 7.5 lpm product flow (2.0 gpm) at 1,379 bar (20,000 psi)
- 4 lpm product flow (1.0 gpm) at 2,068 bar (30,000 psi)
- Low product holdup volume (<1 liter)
- Small batch capable (minimum 12 liters)
- Complete package unit including motor starter panel and process interlocks
- All product paths are sanitary grade and BPE compliant
- All instruments and valves are anitary grade, BPE compliant
- On board data acquisition for complete batch record audit trail
- Multi-point temperature sensing for assured SIP process
- On board flow meter to measure product and CIP flow rates
- Ultra Clean In Place (UCIP) using supplied feed pump or your CIP system pump
- 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, materials certifications and calibrations
- On site start-up assistance, operator and maintenance training, SAT and IQ/OQ execution by our technical staff

Model shown is subject to change depending on options selected

M-7125 and M-7250 Aseptic Microfluidizer Processors Provide Superior Results For Pilot and Production Environments

Recommended for 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 sterility that always passes 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
- More efficient processing, usually requiring fewer passes than other processing machinery
- 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. Asceptic Microfluidizer processors include Steam in Place (SIP) and Ultra Clean In Place (UCIP) eliminating the need for disassembly and Clean Out of Place (COP). Data recording and validation support documentation including IQ/OQ is included to ensure your ability to comply with 21CFR part 11 guidelines.

Specifications

	M-7125	M-7250
Pressure Range	Up to 689, 1379, or 2068 bar (10,000, 20,000 or 30,000 psi)	
Product Flow Rate	Up to 7.56 lpm (2.0 gpm)	Up to 15.12 lpm (4.0 gpm)
Product Feed Temperature Range	-10°C to 75°C (14°F to 165°F)	
Power Requirement	18.6 kw (25 hp)	37.3 kw (50 hp)
Utility Requirements	• Cooling water for hydraulic oil heat exchanger, preferably tower or city water • Cooling water for product heat exchanger, preferably chilled water loop • Compressed air for feed pump and cycling control switches requires 0.65 m^3/min @ 6.2 bar (23 scfm @ 90 psi) with -37° C to –18° C (-35° F to 0° F) dew point • Sterile steam 22.6 kg/hr @ 2.4 bar (50 lbs/hr @ 35 psi) minimum • Sterile compressed air for product path cool/dry down, 0.085 m^3/min @ 1 bar (3 scfm @ 15 psi)	
Dimensions (L x W x H)*	272 x 161 x 211 cm (107" x 63.3" x 83")	
Weight with oil*		1,592 kg (3,510 lbs)

*all weights and dimensions are approximate

Aseptic Package Includes

- Steam In Place (SIP) with multiple RTDs to assure complete sterilization
- Ultra-Clean-In-Place (UCIP)
- Heat exchanger with product temperature control, pharma grade, double tubesheet style
- Flow meter for batch monitoring and validation
- Yokogawa data acquisition station for temperatures, pressures and flows
- Product wetted surfaces at 20Ra max
- IQ/OQ documentation and execution
- Factory Acceptance Testing (FAT) and Site Acceptance Test (SAT)
- Feed pump, sanitary cGMP grade
- 21 CFR part 11 compliant for electronic signature and batch record keeping
- Motor starter panel with machine and process interlocks
- CE compliant

Available Options

- Motor voltage as needed
- ATEX compliant version available
- Explosion proof (XP) version available

Microfluidics

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