

M-7250 CP Aseptic BioPharmaceutical Microfluidizer® Processor

TB-BP72.A-3

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)
- Low product holdup volume (<1 liter)
- Small batch capable (minimum 12 liters)
- Complete package unit including motor starter panel and process interlocks
- Pulse free high shear processing
- 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
- 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-7250 CP Aseptic Microfluidizer Processor Provides 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
- Constant pressure control system means lower stress = lower maintenance
- 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

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.

Operating Principle

The digitally controlled constant pressure M-7250CP series Microfluidizer high shear fluid processors achieve a nearly uniform pressure profile. Coupled with its proprietary fixed geometry interaction chambers, the constant pressure equipment ensures that all product is exposed to the same level of shear force. This means that fewer passes are required in production and translates directly to cost savings. Operating at constant process pressure also minimizes component stress, resulting in longer life and significantly increasing machine reliability.

The intelligent built-in pump position transducers automatically adapt to changing requirements and easily maintain constant process pressure. This full digital control of the dual high pressure intensifier pumps ensures that the product flows at constant pressure and velocities through the interaction chambers. This control eliminates pressure spikes, provides extremely uniform processing, and permits the M-7250 CP system to operate more quietly and efficiently.

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. Aseptic Microfluidizer processors include 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.



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Specifications

Pressure Range	Up to 690 bar (10,000 psi) and 1379 bar (20,000 psi)
Product Flow Rate (based on water)	Up to 15 lpm @ 690 bar (4 gpm @ 10,000 psi) and up to 7.5 lpm @ 1379 bar (2 gpm @ 20,000 psi)
Product Feed Temperature Range	-10°C to 75°C (14°F to 165°F)
Power Requirement	37.3 kw (50 hp)
Utility Requirements	<ul style="list-style-type: none"> 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 m³/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 m³/min @ 1 bar (3 scfm @ 15 psi)
Dimensions (LxWxH)*	272 x 161 x 211 cm (107" x 63.3" x 83")
Weight*	1,592 kg (3,510 lbs)

*all weights and dimensions are approximate

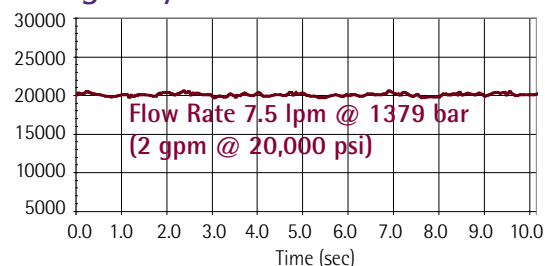
Aseptic Package Includes

- 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

Pressure Profile of M-7250-20 CP Digitally Controlled Processor



Microfluidics reserves the right to change specifications without notice.

