



Instruction Manual Jacketed Liposome Extruder

Operation Manual for Jacketed Temperature-control Liposome Extruder

Catalog No. GJE-100mL





Instruction Manual Jacketed Liposome Extruder

1. Open-box Inspection

Check whether there is any packing damage. Refer to the shipping list for the integrity of the product.

2. Product Introduction


2.1 Brief Introduction


Genizer jacketed temperature-control liposome extruder is made of pharmaceutical grade 316L stainless steel approved by FDA and GMP, finished by laser boring on stainless steel micron-pore supporting plate, which can guarantee the maximum pressure resistance of filter membrane. The main application of extruder is nanoparticulation and homogenization of pharmaceutical liposome and emulsion. The extruder prepares liposomes and emulsions with 30-2000 nm track-etched membrane. The extruder needs to be used in conjunction with pressurized inert gas, typically connected to a 5-10 MPa medium-pressure nitrogen cylinder. Compressed nitrogen at 80-500 psi is input under the action of a pressure regulator, allowing the material to pass evenly through the filter membrane under pressure, ultimately completing the extrusion. With the jacketed temperature-control design, the equipment is able to heat or cool materials, therefore applicable to the high-viscosity products.


2.2 Specifications


Maximum pressure	500 psi
Final particle size	30-2000 nm
Maximum concentration	200 mg/ml
Operation capacity	10-10,000 ml
Operating temperature	0-100°C
Product material	316L stainless steel
Working condition	Medium-pressure inert gas
Material standard	Pharmaceutical grade


3. Safety Instruction


 **Attention:** The designed maximum pressure is 500 psi. Please do not exceed this pressure during operation.

 **Danger:** Check the O-rings routinely and replace them when necessary. Damaged or worn O-rings may break suddenly and cause a sudden decompression of the extruder. Fracture of O-rings may also lead to high-speed discharge of liquid materials.

 **Warning:** The jacket of the extruder may be overheated in operation and cause burns. Please be careful.


 **Warning:** Lift and move the extruder carefully to avoid crush injuries.








 **Warning:** Genizer jacketed extruder should be operated in accordance with related safety requirements. Operators must wear protective clothing and operate the extruder in hood or shelter. Any personnel or property loss due to any violation of safety requirements should be assumed by the organization or individual using it.

 **Warning:** Using original parts to replace worn or damaged parts. Replacement with non-original parts will not be warranted.

4. Parts List

Regular parts of Genizer jacketed temperature-control extruder are listed below:

Part No.	Part Name	Quantity	
1	Extruder Base	1	

Part No.	Part Name	Quantity	
2	Filter Support Base	1	
3	Luer Connector	1	
4	Temperature Control Jacketed Barrel	1	
5	Inlet Cap Screw	1	
6	Extruder Top	1	
7	Laser Disc	1	
8	Small O-ring	2	
9	Middle O-ring	2	

Part No.	Part Name	Quantity	
10	Large O-ring	1	
11	Gasket	4	
12	Wing Nut	4	
13	High Pressure Nitrogen Tubing	1	
14	Large Pore Support Disc	1	

The following items are optional parts.

- a. Polycarbonate liposome membrane
- b. Drain disc

5. Assembly Procedure

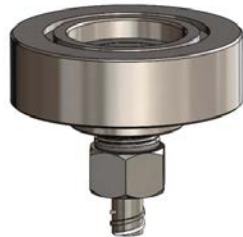
The table below describes the assembly steps of 100mL Genizer jacketed temperature-control extruder. Refer to the Parts List in the assembly.

Step 1



Remove unnecessary devices in the operation area. And then Place the extruder base① onto a proper platform.

Step 2



Tighten the screws of the filter support base② and the luer connector③ with a spanner. (Pre tightened at the factory)

Step 3



Place the mounted units in step 2 onto the extruder base①.

Step 4



Mount the large O-ring⁽¹⁰⁾ large pore support disc⁽¹⁴⁾, and laser disc⁽⁷⁾ on the filter support base⁽²⁾ in order.

Attention: (1) The laser disc⁽⁷⁾ should be placed on top of the large pore support disc⁽¹⁴⁾; (2) The smooth side face of the laser disc⁽⁷⁾ should upward when mounted.

Step 5



Place the nano-membrane and drain disc of specific size on the laser disc ⁽⁷⁾carefully.

Attention: (1) The nano-membrane should be placed on top of the drain disc; (2) the nano- membrane must be placed flatly without any wrinkle or bubble. Wet and then flat it to make it fixed.

Step 6



(1) Assemble the middle O-ring⑨ into the groove at the bottom of the temperature control jacketed barrel.④ (2) Place the temperature control jacketed barrel④ on the filter support base②.

Step 7



Place two small o-rings⑧ into the sealing ring groove of the inlet cap screw⑤ and fix them. (Installed at the factory.)

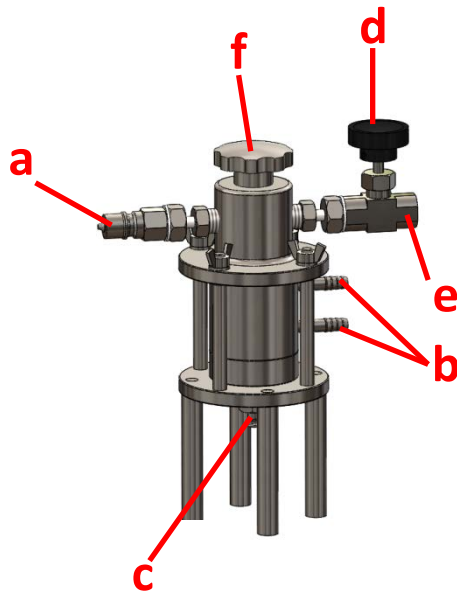
Step 8



(1) Assemble the middle O-ring⑨ into the groove at the bottom of the extruder top⑥. (2) Mount the extruder top⑥ and tighten it in order with gaskets⑪ and wing nuts⑫. (3) Tighten the inlet cap screw⑤ by screwing it

into the threaded hole of the extruder top⑥.

Step 9



a: connected to the female of the provided high-pressure nitrogen tubing⑬

b: connected to the temperature control water pipe if needed

c: connected to product collection tubing (provided luer outlet hose)

d: exhaust valve

e: gas release port

f: feed port (Unscrew it when feeding)



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6. General Operating Steps

6.1 Operation Steps

(1) Follow step 9 to connect all the tubings. Connect the other end of the high-pressure nitrogen tubing⁽¹³⁾ to the nitrogen cylinder with regulator. And if needed, connect the chiller to the joint (b) on the temperature-control jacketed barrel to cool or heat the material to a specified temperature.

(2) Open the exhaust valve (d) on the top of the extruder anticlockwise to exhaust gas first.

Note: Make sure the regulator knob is on the losing position.

(3) Open the feed port (f) and fill in no more than 10ml unprocessed material. Then screw the cap screw back and close the exhaust valve (d) clockwise to be ready for the operation.

(4) Turn the gas cylinder knob to let the nitrogen flow, then set the operational pressure by turning the regulator knob clockwise until the pressure registers as your requested value. Materials extruded by the nitrogen will then be pushed through the nano pores in the nano membrane to the product collection tubing (c).

(5) Observe the material collected, and keep the nitrogen flowing until the extrusion process finished.



Attention: (1) After finishing the extrusion, turn off the gas cylinder knob first. (2) Depressurize the pressure by opening the exhaust valve on the extruder top. (3) After depressurization, close the exhaust valve. Then, turn off the regulator knob to finish the whole process.

6.2 General Cleaning

In general, please follow the steps below to clean the extruder. Some special compounds should be cleaned specifically.

1. The extruder should be cleaned immediately after operation. Disassemble the extruder according to Parts List. More recommended way is to use sonication to clean the extruder.

2. We recommend non-phosphate detergents. Keep the water fairly warm and use a brush to clean parts difficult to reach. Clean the extruder with warm soapy water and then wash with plenty of tap water.

3. Rinse the components under tap water and then wash with distilled water a few more times.

4. All stainless steel parts should be cleaned with 70% ethanol solution. The O-rings must be removed before the wash, or they may get corroded in organic solvents.



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7. Trouble Shootings

7.1 Please reassemble the extruder if there is any gas or material leakage. Check if all O-rings are correctly mounted, and if the wing nuts or any fastener is missed.

7.2 The following factors may make the extruding slow:

7.2.1 The extruding gets incredibly slow if a nano-membrane with small pore size is used to filter materials with large-particle size. It is recommended that the material be filtered first through nano-membrane with large-pore size before the application of the small-pore one.

7.2.2 The filtration resistance becomes excessively high when the material gets condensate at the current operation temperature. Please change the temperature.

7.2.3 The filtration capacity decreases dramatically when the nano-membrane is blocked. Replace the nano-membrane in this case.

7.2.4 The material mixtures are not homogeneous can cause the blockage of the membrane. Please optimize the pretreatment.



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7.3 Check if the connection between the temperature-control jacketed barrel and chiller is correct and whether the circulation is smooth when the temperature-control jacketed barrel remains unheated.



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Jacketed Liposome Extruder

Genizer Liposome Extruder System

Solution for liposome and nanoparticle extrusion

	Catalog No.	Thermo-control	Power mode	Support plate	Maximum pressure	Dimension L×W×H(cm)/Weight(kg)	Nano membrane
			Air				
	HandExtruder-1ml-RT	Optional		Micron pore plate	150 psi	23×17×33/2 (jacketed)	
	HandExtruder-1ml					23×17×13/2	
Test Scale	GJE-10ml	Included	Y	Laser & Large pore support disc	500 psi	23×13×25/4 (jacketed)	30 nm
	GJE-100ml	Included	Y	Laser & Large pore support disc	500 psi	23×20×32/7 (jacketed)	50 nm
Pilot Scale	GJE-800ml	Included	Y	Multi-layer sintered plate	500 psi	25×25×37/20 (jacketed)	80 nm
	GJE-3000ml	Included	Y	Multi-layer sintered plate	500 psi	30×25×55/45 (jacketed)	100 nm
Production Scale	GJE-10000ml	None	Y	Multi-layer sintered plate	500 psi	45×40×65/130 (jacketed)	200 nm
Customize Scale	GJE 0-800ml	Included	Y	Multi-layer sintered plate	up to 3,000 psi	TBD (jacketed)	400 nm
							800 nm

Notice: The dimension, structure and parameter should be subject to the final product.