Operation Manual of Liposome Hand-Extruder

Catalog No. HandExtruder-1mL;
HandExtruder-1mL-RT

1. Open-box Inspection

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

2. Product Introduction

2.1 Introduction

The liposome and lipopolyplex are used for drug, protein and gene delivery. Liposome Hand-Extruder system is applicable for formulation design of liposome and lipopolyplex. The parts contacted with the medium are made of 316L stainless steel or material such as titanium alloy which is more resistant to strong acid and base. The protective film outside of the gas-tight syringe gives the extra-protection for syringe and user.

2.2 Specification

Maximum pressure	150 psi
Finished product size	50 nm-500 nm
Maximum concentration	200 mg/mL
Operation capacity	0.5 mL / 1.0 mL
Temperature control	Optional
Material standard	Pharmaceutical grade

3. Safety Notes

⚠ **Warning:** The syringe is made of glass, please check if the syringe cylinder has any cracks before use; additionally, do not overexert yourself during operation.

⚠ **Danger:** Always check the wear pattern of all O-rings, and replace them if necessary. During the operation, damaged or worn O-rings may rupture suddenly, which could lead to a sudden decompression of the extruder.

⚠ **Warning:** Gently lift and move equipment to avoid personnel injury.

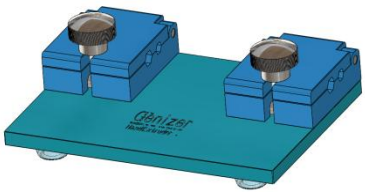
⚠ **Warning:** Genizer™ Hand-Extruder should be performed in accordance with the relevant safety requirements. The operator must use protective clothing or shelter. The operator should be responsible for any personal or property damage caused by safety requirements violations.

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

4. Parts List

Genizer™ Liposome Hand-Extruder includes the following parts:

Part No.	Part name	Quantity	
1	Container nut	2	
2	Housing	1	 For HandExtruder-1mL  For HandExtruder-1mL-RT

Part No.	Part name	Quantity	
3	O-ring support	2	
4	O-ring	2	
5	Micro pore disc	2	
6	Stabilizer	1	

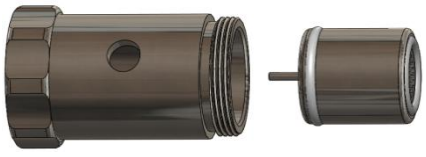
The following items are optional parts:

a. Nanopore Track-Etched Liposome Membranes

b. 0.5ml or 1.0ml gas-tight syringes

5. Assembly Procedure

The following table details the assembly steps for the Genizer™ liposome Hand-Extruder. Refer to the parts list to complete the assembly.

Step 1 	Screw a container nut (1) onto the housing (2) (leaving a half-turn gap without fully tightening).
Step 2 	Insert the micro pore disc (5) into the O-ring (4). Assemble the combined O-ring assembly onto the rear of the O-ring support (3), as shown in the diagram.
Step 3 	Placing the assembled unit from Step 2 into the housing (2), leaving the rear end slightly exposed to facilitate the membrane placement.

Step 4

Carefully place the track-etched membrane onto the assembly in Step 3 using tweezers.

Note: Ensure the membrane is concentric with the O-ring and wrinkle-free. Wetting the membrane helps with placement.

Step 5

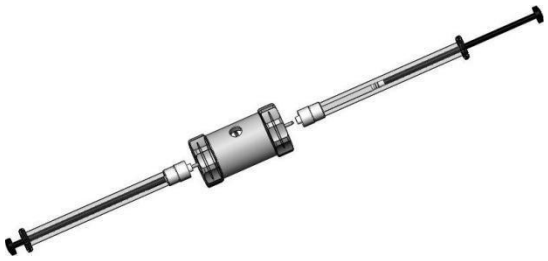
Following Step 4, carefully align and insert the other assembled unit from Step 2 into the housing (2). Apply even pressure to push it all the way down until it touches the container nut (1).

Note: Avoid rotating the O-ring support (3) during pushing to prevent damage to the track-etched membrane.

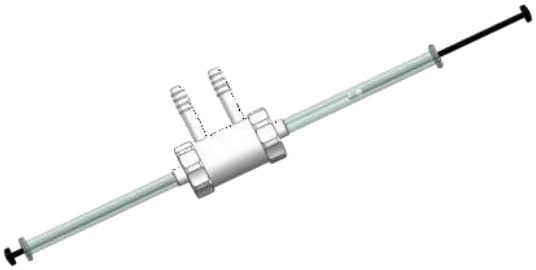
Step 6

Screw the other container nut (1) onto the housing (2). Tighten by hand in a clockwise direction until slight resistance is felt. Then, using both hands, hold each container nut (1) with a hand, and tighten simultaneously in both directions until noticeable resistance is felt, then stop.

Step 7



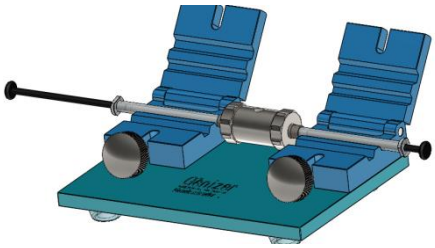
For HandExtruder-1mL



For HandExtruder-1mL-RT

Connect the gas-tight syringes to the container nuts: one syringe is filled with the material as the feeding syringe, and the other is empty as the collector syringe.

Step 8



Place the assembly from Step 7 into the grooves of the stabilizer (6). Cover it with the plastic top and tighten the nuts to secure it.

Note: The stabilizer (6) has two groove sizes. The smaller groove fits 0.5ml syringes, and the larger groove fits 1.0ml syringes.

6. General Operating Steps

6.1 Operation Steps

After completing the installation as outlined above, start by pushing the piston of the gas-tight syringe filled with the material to begin operation. Use the empty syringe on the opposite side as a material collector. If the material has been properly pre-treated and the track-etched membrane with the correct pore size is selected, the material will slowly flow into the empty syringe. After each unidirectional extrusion, rotate the extruder to switch the positions of the syringes, then push the piston of the collector syringe to resume extrusion process. Repeat these steps until the material reaches the desired size, or replace the track-etched membrane with a smaller pore size if needed.Typically, achieving the desired particle size may require more than ten extrusions with a standard formulation. Multiple trials may be needed to optimize the process during initial experiments.

Note: Handle operations with care, as the syringe cylinder is made of glass.

6.2. General Cleaning Procedure

The following steps are for general cleaning of the extruder; specific compounds may require special cleaning procedures.

1. Rinse the syringe and extruder with isopropyl alcohol, deionized water, or a low-concentration detergent solution, depending on the specific application. If a detergent solution is used, immediately rinse the syringe and extruder with a large amount of deionized water.

2. After cleaning, rinse thoroughly with deionized water and dry.

3. If an ultrasonic cleaner must be used, clean only the needle with it. After cleaning in the ultrasonic cleaner, rinse immediately with deionized water and dry.

Important Note:

1. Do not allow the syringe to come into contact with any solvent other than deionized water or alcohol. Certain organic solvents may react with the adhesive used to secure the threaded insert on the syringe needle, potentially weakening the bond strength between the syringe barrel and the insert. For the same reason, never immerse the syringe in any solvent.

2. Grooved O-rings should not be soaked in alcohol solutions for

extended periods, as this may lead to a decrease in sealing performance.

3. The filter membrane is intended for single-use only in liposome preparation and should not be reused.

7. Trouble Shootings

7.1 When the extruder is leaking, please disassemble it to inspect whether all O-rings are in good condition and installed correctly. Also, check if the fasteners are loose.

7.2 The following factors are likely to cause slow filtration:

7.2.1 Using an inappropriate-sized liposome membrane. Filtering large particle materials through a nano-pore membrane with a pore size that is too small can significantly slow down the process. It is recommended to use a nano-pore membrane with a larger pore size initially for filtration, and then switch to a smaller one if necessary.

7.2.2 Coagulation of temperature-sensitive materials at the operating temperature, resulting in increased filter resistance. Adjusting the operating temperature is recommended.

7.2.3 Blockage of the nano membrane, greatly reducing filtration capacity. Replacement is advised.

7.2.4 Uneven distribution of the material mixture may also cause slow filtration. Improve pretreatment processes to address this issue.