

LIPEX® Flow Thermobarrel Extruder packages

OVERVIEW

LIPEX® Flow Thermobarrel Extruders are the industry-leading bench-top extruders for R&D and cGMP manufacturing of liposomal formulations in both academia and industry.

The innovative and patent-pending design maximizes the effective filtration area, resulting in lower extrusion pressures and high-flow processes. This translates to increased throughput, a wider formulation application range, faster processing times, and minimized process risks

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| <p>1 HIGH THROUGHPUT</p> <p>.....</p> | <p>2 WIDE OPERATING RANGE</p> <p>.....</p> | <p>3 FAST PROCESSING TIME</p> <p>.....</p> |
| <p>4 MINIMIZES PROCESS RISK</p> <p>.....</p> | <p>5 6X INCREASE IN EFA*</p> <p>.....</p> | <p>6 3X INCREASE IN MAOP**</p> <p>.....</p> |
| <p>7 UP TO A 50 % DECREASE IN REQUIRED EXTRUSION PRESSURE COMPARED TO PREVIOUS LIPEX® MODELS (individual results will be formulation and process dependent)</p> <p>.....</p> | | |

*EFA = Effective Filtration Area **MAOP = Maximum Allowable Operating Pressure

The units are designed to produce a homogenous population of large unilamellar vesicles from a non-homogenous population of multi-lamellar vesicles. The unilamellar vesicles are formed by utilizing a constant pressure force of between 100 and 2400 psi to force the vesicles through filters of a predefined pore size. These units have a maximum operating pressure and temperature of 2450 psi and 80 °C, respectively. The side walls of the thermobarrel and filter support are jacketed to provide efficient temperature control of the extruder for optimal size reduction results.

PACKAGE CONTENTS

- (1x) LIPEX® Flow Thermobarrel Extruder
- (1x) Package of polyester drain discs (100/pack)
- (1x) Package of polycarbonate filters with 100 nm pore size (100/pack)
- (1x) Spare O-ring set
- (1x) High pressure nitrogen line
- (1x) Turnover package USB
 - Operating manual
 - Declaration of conformity
 - Certificate of inspection & testing

TECHNICAL SPECIFICATIONS

LIPEX® Flow Model	10 mL	100 mL	1000 mL
MAOP*			
• psig	2450	2450	2450
• bar	170	170	170
MAOT (°C)**	80	80	80
Min. Extrusion volume	1 mL	20 mL	100 mL
Max. Extrusion volume	10 mL	100 mL	1000 mL
Weight (kg)	3	7	25
Material			
• Body	316 L Stainless steel		
• O-Ring	EPDM		
Surface finish	Mechanically finished		
			

*MAOP = Maximum Allowable Operating Pressure **MAOT = Maximum Allowable Operating Temperature

REQUIRED ANCILLARY EQUIPMENT/SUPPLIES

The following is a list of commonly used ancillary equipment and materials required for efficient operation of the extruder.

- polyester drain disc (included)
- polycarbonate filter (included)
- heated re-circulator
- high pressure gas cylinder (nitrogen)
- gas regulator with a minimum delivery pressure of 2500 psi

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Evonik Operations GmbH
Health Care Business Line
Drug Delivery & Medical Device
Solutions

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