

Saint-Gobain Life Sciences – Bioprocess Solutions

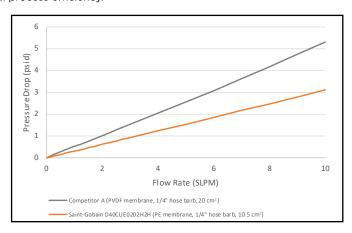


PureFlo® PE Disc Capsules

PureFlo® PE disc capsules are gamma-irradiatable, easy-to-use filtration units, ideally suited for integration into small scale single-use sterile assemblies. The hydrophobic polyethylene (PE) membrane demonstrates exceptional flow performance in venting and compressed gas applications.

Superior Flow Performance

PureFlo® PE capsules incorporate a sterilizing grade 0.2 μ m membrane that exhibits a lower pressure drop compared to other hydrophobic membranes such as PVDF. The superior flow performance results in a light-weight, compact filter designed to promote optimal process efficiency.



Engineered Filtration Solutions

To meet the needs of an innovative and rapidly growing industry, and in addition to the standard product offering, Saint-Gobain offers a collaborative service with a dedicated team of engineers and subject matter experts to develop specialized filtration solutions that are tailored to achieve optimal performance. Please contact us for more information.

Features / Benefits



Inherently Hydrophibic



Gamma-Irradiatable



High Flow Rate



Animal-Derived Component Free



Sterilizing Grade



100% Integrity Tested

Typical Applications

- Bioreactor Vent
- Moisture Barrier
- Compressed Gas
- Fermentation Tank Vent
- Bottle or Carboy Vent



Technical Summary

Materials	
Membrane	Polyethylene (PE)
Molded Components (shell)	Polyethylene (PE)

Membrane Configurations			
Membrane	Description	Minimum Bubble Point (at 22 °C)	
UE020	0.2 μm	1.2 bar 17.4 psi (in 60% isopropyl alcohol, 40% water)	

Measurements (nominal)				
Size	Outside Diameter (mm)	Body Length Without Fittings (mm)	Filtration Area (cm²)	
D13R	16	3.7	0.8	
D25C	33	5.45	4.6	
D40C	45.5	8	10.5	

Operating Conditions			
Maximum Temperature	60 °C		
Maximum Inlet Pressure (at 22 °C)	2.1 bar 30 psi		
Maximum Forward Differential Pressure (at 22 °C)	2.1 bar 30 psi		

Sterilization		
Gamma	Up to 50 kGy	
Ethylene Oxide	Testing is recommended.	

Shelf Life

Non-sterile products have a shelf life of 3 years after the date of manufacture.

Traceability

For traceability and easy identification:

- A Certificate of Conformance is provided with each capsule.
- Each filter bag and box are labeled with the product part number, lot number, and identifying characteristics.
- Each 25 mm and 40 mm disc capsule is engraved with the product lot number and identifying characteristics.

Regulatory & Stewardship

Saint-Gobain's PureFlo® PE D13R, D25C, and D40C Disc Capsules were designed, manufactured, and qualified with an ISO 13485 certified Quality Management System. For more information, please refer to the product <u>Validation Guide and Regulatory Information Overview (RIO)</u>.

Category	Standard or Reference Test
Cleanliness	USP <85> Bacterial Endotoxin Test
Biocompatibility	USP <88> (USP Class VI Plastics) Biological Reactivity Tests, In Vivo
Food Contact	USP 21 CFR 177 FDA Indirect Food Additive
Bacterial Retention	Quantitative retention of 10 ⁷ CFU/cm ² Brevundimonas diminuta per ASTM methodology
Animal-derived Components	No animal-derived material is intentionally added or used during the manufacture of PureFlo® PE D13R, D25C, and D40C Capsules.
RoHS	Restriction of Hazardous Substances (RoHS 3) Directive 2015/863
REACH	REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Article 57, Regulation No. 1907/2006)

Lot Release Criteria

Each PureFlo® PE D13R, D25C, and D40C Disc capsule product lot is sampled and tested for conformity to the following criteria:

Criteria	Description
Integrity (membrane)	Each filter (100%) in a lot is integrity tested during the manufacturing process.
Integrity (housing)	A representative sample of the lot is tested to meet specification.
USP Bacterial Endotoxins	A representative sample from the lot is tested to confirm that an aqueous extraction of the product contains <0.25 EU/mL as determined by the Limulus Amebocyte Lysate (LAL) Test.

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PureFlo® PE **Disc Capsules**

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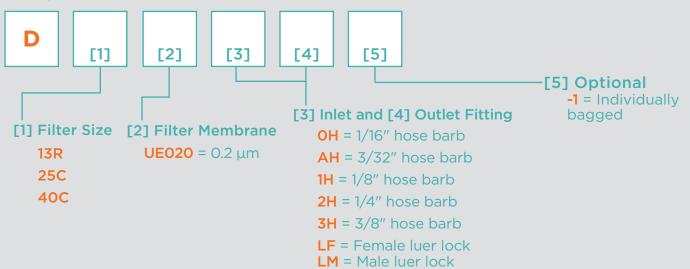
PRODUCT TECH SNAPSHOT: (Values are nominal. Please see Technical Summary for additional information)

Filter Size	Body Diameter (mm)	Body Length Without Fittings (mm)	Filtration Area (cm²)	Typical Flow Performance* (in air, 22 *C, vent condition)
D13R	16	3.7	0.8	D13RUE0201H1H - 3 psid at 1 L/min
D25C	33	5.45	4.6	D25CUE0201H1H - 0.9 psid at 1 L/min
D40C	45.5	8	10.5	D40CUE0202H2H - 0.3 psid at 1 L/min

* IMPORTANT: The flow performance of a filter capsule is dependent on several variables including the process fluid characteristics, operating conditions, filter surface area, pore size and fittings. The above values are approximate for example part numbers and provided for reference only. Actual values may vary. For application guidance and flow performance information for a specific part number please contact your local Saint-Gobain representative.

Ordering Guide







Don't see what you're looking for?

Customer Service

50 W. Watkins Mill Rd. Gaithersburg, MD 20878 Tel: (301) 407-2720 Fax: (240) 566-5774 Email: info.ft@saint-gobain.com

www.biopharm.saint-gobain.com

Please let us know! We're here to help.

PLEASE NOTE:

Not all fittings are available for all filter sizes. Please refer to the next page of the brochure for a standard list of fitting available for each filter size.

PureFlo® PE Disc Capsule Ordering Guide (continued)

Table A. Inlet and outlet fitting option availability					
Inlet/Outlet Fitting	Description	D13R	D25C	D40C	
ОН	1/16" hose barb	•	^	^	
АН	3/32" hose barb	•	^		
1H	1/8" hose barb	•	^	^	
2H	1/4" hose barb		^	^	
3H	3/8" hose barb		^	^	
LF	Female luer lock	•	•	•	
LM	Male luer lock	•	•	•	

^{• =} fitting is available (if it is a hose barb, it is straight)

^{^ =} fitting is available (if it is a hose barb, it is stepped or tapered)



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<u>Contact us today for:</u> <u>Consultations • Samples • Quotes • Orders</u>

For registered access to Saint-Gobain Product Validation Summaries, CLICK HERE

IMPORTANT: It is the user's responsibility to ensure the suitability and safety of Saint-Gobain Life Sciences products for all intended uses and that the materials to be used comply with all applicable medical regulatory requirements. Saint-Gobain Life Sciences assumes no responsibility for any product failures that occur due to misuse of the materials it provides arising out of the design, fabrication or application of the products into which the materials are incorporated.

WARRANTY: For a period of 12 months from the date of first sale, Saint-Gobain Life Sciences warrants this product to be free of defects in materials and workmanship. Our only obligation will be to replace any portion proving defective, or at our option, to refund the purchase price there of.

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