

ПОЛИЭТИЛЕНОВАЯ ПЛЕНКА PUREFLEX



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PureFlex™ Single-Use Process Container Films

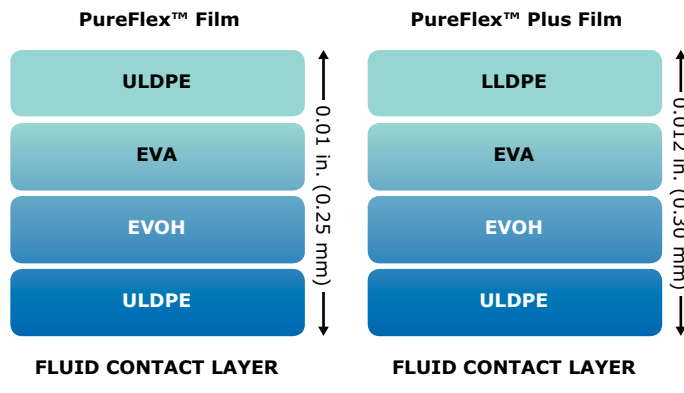
Flexible, robust and chemical-resistant materials used for the construction of single-use process containers

Containers made with PureFlex™ films are employed throughout the biopharmaceutical production process and are free of animal-derived components. They are used in the construction of our Mobius® assemblies and NovaSeptum® sterile sampling products, which are customized for any application.

PureFlex™ Film

PureFlex™ film is a high-purity, medical-grade, coextruded film designed to provide strength, flexibility, low gas permeability, and an inert product contact layer. The fluid contact material is made of ultra-low density polyethylene (ULDPE). The gas barrier layer is made of polyethylene vinyl alcohol copolymers (EVOH). The outer layers are made of ethylene vinyl acetate (EVA) and ULDPE. PureFlex™ film contact layers comply with the Food and Drug Administration (FDA) regulation 21 CFR 177.1520.

PureFlex™ film is used at every step in the drug manufacturing process, including media and buffer preparation, cell culture, purification, intermediate product storage and mixing, sterile sampling, and fill and finish operations. This versatility allows for the use of a single film for the full process, limiting validation and implementation effort.



PureFlex™ Plus Film

For particularly demanding applications often encountered in large-volume operations (>500L), additional robustness may be required to assure single-use process container integrity. PureFlex™ Plus film is constructed with a tough, linear low-density polyethylene (LLDPE) outer layer. This rugged outer layer increases the film's resistance to leak formation through abrasion, puncture, stretching, and tearing. The inner layers of PureFlex™ Plus film, including the product contact layer, are identical to PureFlex™ film, maintaining the same extractables profile and gas barrier properties. While PureFlex™ Plus film is designed for use in physically stressful applications, it remains suitable for use throughout the manufacturing process.

Physical Data (Post-gamma irradiation)

Properties	Tests	PureFlex™ Film Average Values ¹	PureFlex™ Plus Film Average Values ²
Tensile Strength	ASTM® D882	2700 psi (18.6 Mpa)	2245 psi (15.4 Mpa)
Elongation	ASTM® D882	570%	630%
Yield Strength	ASTM® D882	1360 psi (9.4 Mpa)	2000 psi (13.7 Mpa)
Secant Modulus	ASTM® D882	37 kpsi (255 Mpa)	39 kpsi (269 Mpa)
Toughness	ASTM® D882	9100 in.-Lbf/in. ³ (63 M J/m ³)	10500 in.-Lbf/in. ³ (73 M J/m ³)
Seam Strength	ASTM® D882	18 Lbf/in. (32 N/cm)	20 Lbf/in. (36 N/cm)
O ₂ Transmission Rate	ASTM® F1307 at 23°C	0.063 cc/100 in. ² /24 hrs (0.98 cc/m ² /24 hrs)	0.017 cc/100 in. ² /24 hrs (0.26 cc/m ² /24 hrs)
CO ₂ Transmission Rate	ASTM® F2476 at 23°C	0.13 cc/100 in. ² /24 hrs (92 g/m ² /24 hrs)	<0.065 cc/100 in. ² /24 hrs (<46.02 g/m ² /24 hrs)
MVTR	ASTM® F1249 at 23°C	0.034 g/100 in. ² /24 hrs (0.53 g/m ² /24 hrs)	0.067 g/100 in. ² /24 hrs (1.1 g/m ² /24 hrs)
Haze	ASTM® D1003	23%	30%
Glass Transition Temperature	ASTM® D5026	-15°F (-26°C)	-13°F (-25°C)
Film Thickness	ASTM® D374	0.01 in. (0.25 mm)	0.012 in. (0.30 mm)
Operating Temperature Range ³		-112 – 140°F (-80 – 60°C)	-112 – 140°F (-80 – 60°C)

¹PureFlex™ film values reported after gamma irradiation at > 45 kGy.

²PureFlex™ Plus film values reported after gamma irradiation at 25-40 kGy.

³Freezing requires the film to be supported.

Biocompatibility Data for PureFlex™ and PureFlex™ Plus Films (Post-gamma irradiation at ≥ 40 kGy)

Properties	Tests	Result
USP Class VI	USP <88>	Passed
Cytotoxicity	USP <87>	Passed
Bacterial Endotoxin	USP <85>	Passed
Heavy Metals	USP <661>	Passed
Buffering Capacity	USP <661>	Passed
Non-volatile Residuals	USP <661>	Passed
Residue on Ignition	USP <661>	Passed
Hemolysis	ISO® 10993-4	Passed
Appearance	EP 3.2.2.1	Passed
Acidity and Alkalinity	EP 3.2.2.1	Passed
Absorbance	EP 3.2.2.1	Passed
Reducing Substances	EP 3.2.2.1	Passed
Transparency	EP 3.2.2.1	Passed
Particulate Matter	USP <788>	Passed



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