

PureFlex™ Single-Use Process Container Films

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

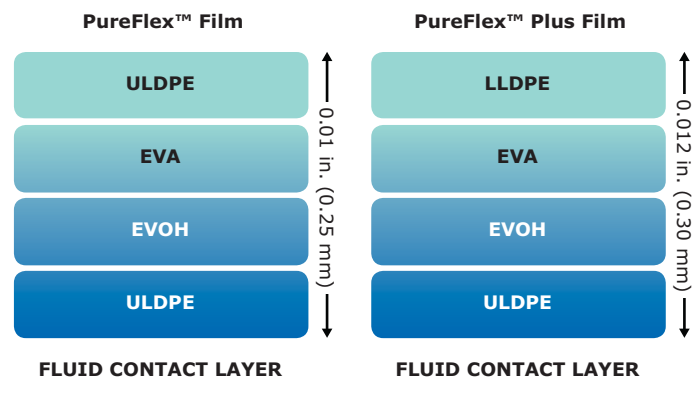
PureFlex™ film is used to construct our Mobius® single-use assemblies and Novaseptum® sampling bags. These single-use products are used in biopharmaceutical processes, improving efficiency and productivity while reducing the risk of contamination.

PureFlex™ Film

PureFlex™ films are high-purity, medical-grade, coextruded films designed with low gas permeability and an inert product contact layer. PureFlex™ films provide great process flexibility that enable biomanufacturers to scale their process with a single fluid-contact material.

Both PureFlex™ and PureFlex™ Plus films provide a fluid contact layer made of ultra-low-density polyethylene (ULDPE). The gas barrier layer is made of polyethylene vinyl alcohol copolymers (EVOH). An ethylene vinyl acetate (EVA) layer helps maintain flexibility. While **PureFlex™ film** uses the same ULDPE resin in its outer layer, **PureFlex™ Plus film** is constructed with a tougher, linear low-density polyethylene (LLDPE) outer layer.

PureFlex™ films can be 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.



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/m3)	10500 in.-Lbf/in.3 (73 M J/m3)
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/m2/24 hrs)	0.017 cc/100 in.2/24 hrs (0.26 cc/m2/24 hrs)
CO ₂ Transmission Rate	ASTM F2476 at 23°C	0.13 cc/100 in.2/24 hrs (92 g/m2/24 hrs)	<0.065 cc/100 in.2/24 hrs (<46.02 g/m2/24 hrs)
MVTR	ASTM F1249 at 23°C	0.034 g/100 in.2/24 hrs (0.53 g/m2/24 hrs)	0.067 g/100 in.2/24 hrs (1.1 g/m2/24 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
Biological Reactivity	USP <88> Class VI	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	Ph. EUR. 3.2.2.1	Passed
Acidity and Alkalinity	Ph. EUR. 3.2.2.1	Passed
Absorbance	Ph. EUR. 3.2.2.1	Passed
Reducing Substances	Ph. EUR. 3.2.2.1	Passed
Transparency	Ph. EUR. 3.2.2.1	Passed
Particulate Matter	USP <788>	Passed
Indirect Food Additives	FDA 21 CFR 177.1520	Passed

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