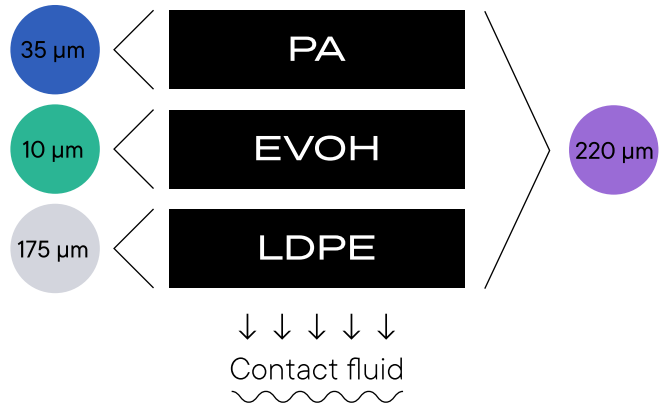


UNE[®]

UNE[®] One - PA/PE multilayer film with PE sealing layer, developed for single-use bioprocess bags. Polyethylene (LDPE) contact layer PA provides safe handling of 35 µm biopharmaceutical fluids. Added gas barrier in form of Ethyl Vinyl Alcohol (EVOH) prevents uncontrolled oxygen and carbon dioxide transmission. Suitable for 2D, 3D and liner bag designs.



UNE[®] One biological and particulate test data (post-gamma irradiation)

DESCRIPTION	PROTOCOL	RESULTS
Cytotoxicity	USP <87>	Pass
Bacterial Endotoxin	USP <85>	Pass
USP Class VI	USP <88>	Pass
Hemolysis	ISO 10993-4	Pass
Particulate Matter	USP <788>	Pass
Non-Volatile Residue	USP <661>	Pass
Residue on Ignition	USP <661>	Pass
Heavy Metals	USP <661>	Pass
Buffering Capacity	USP <661>	Pass
Appearance:		
Opalescence and Color	EP3.2.2.1	Pass
Absorbance	EP3.2.2.1	Pass
Acidity	EP3.2.2.1	Pass
Alkalinity	EP3.2.2.1	Pass
Reducing Substances	EP3.2.2.1	Pass
Transparency	EP3.2.2.1	Pass

All measurements are reported post-gamma irradiation $\geq 20-40$ kGy.