

Flex4Sure™ 3D

100-1000L multi-layer PE 'bag in box' for the storage and handling of bio- pharmaceutical process solutions.

The multi-layer co-extrusion film used for the 3D bags ensures minimized gas permeability, good physical strength, and wide chemical compatibility and biocompatibility of the aseptic storage bags, so that they can be safely used for the storage and transportation of various biopharmaceutical liquids. The standard 3D bags are available in chamber volumes from 100L - 1000L and can be used with a corresponding rigid tote for storage of buffers, culture media, intermediates, or drug substances. Luer connectors, CPC quick connectors, sanitary Tri-clamp connectors, or sterile connectors are available for inlet and outlet tubing and filter capsules to ensure compatibility with upstream and downstream process equipment. A variety of sampling tools can be used, such as needleless samplers, Luer female connectors, and medical heparin caps.



Advantages

- Highly transparent film materials for enhanced visual inspection of process fluids.
- Flexible customization of sizes, tubings, joints, and filters for a variety of biopharmaceutical processes.
- Simplify implementation with chambers that are compatible with a variety of cubical support containers/totes.

Applications

- Storage and transport of buffers and culture media.
- Transport of harvested cell culture fluids.
- Purified component collection.
- Filtration and storage of intermediates.
- Storage and transport of drug substances.

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Simplifying Single-Use Systems
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Technical Parameters

Production Data

	Typical Values
Specification	100L - 1000L - 3-port
Operating temperature	-80 to 60 °C
Sterilization method	Gamma ray irradiation sterilization (25-40 kGy)
Packaging form	Double-layer PE bag vacuum packaging

Typical Values

Film Material Information

Structure	LDPE/EVOH/ULDPE (liquid contact layer)
Thickness	0.325 mm
Compliance	ISO 10993-4: Hemolysis
	ISO 10993-5: Cytotoxicity
	ISO 10993-6: Implantation test
	ISO 10993-10: Irritation and Sensitization tests
	ISO 10993-11: Acute Systemic Toxicity test
	USP<85>: Bacterial Endotoxins-LAL test on request
	USP<88>: Biological reactivity testing, in vivo, class VI
	USP<661>: Plastic Containers European Pharmacopoeia tests, Ch.3.1.5
	ADCF: No animal derived ingredients

Process flexibility is provided by various chamber volumes combined with customised tubing types, sizes and lengths. A wide range of distal connectors (filters, aseptic and hygienic connectors). Manifolds can also be specified for additional process security in critical applications.



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