

Flex4Sure™ 2D

50ml - 50L multi-layer PE pillow bags for the storage and handling of bio-pharmaceutical process solutions.

The multi-layer co-extrusion film used for the 2D pillow 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. Standard 2D chambers with 2 ports 50-500mL and 2D chambers with 3 ports 1-50L.



Advantages

- Good physical strength, chemical compatibility, and biological compatibility of film materials.
- Highly transparent film materials for enhanced visual inspection of process fluids.
- Catering to the needs for storage and transport of various solutions in the biopharmaceutical process.
- Flexible customisation of configuration allowing precise alignment with application needs. Potential for customised chamber volumes.

Applications

- Storage and transport of small-scale buffers and culture media.
- Purified component collection.
- Sample collection and transport.
- Temporary storage and transportation of bulk intermediates.
- Collection, storage, and transport of drug substances.
- Transport of end products.

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Simplifying Single-Use Systems
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Technical Parameters

Production Data

Specification	50-500mL 2-port - 1-50L 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 USP<661>: Plastic Containers European Pharmacopoeia tests, Ch.3.1.5 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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