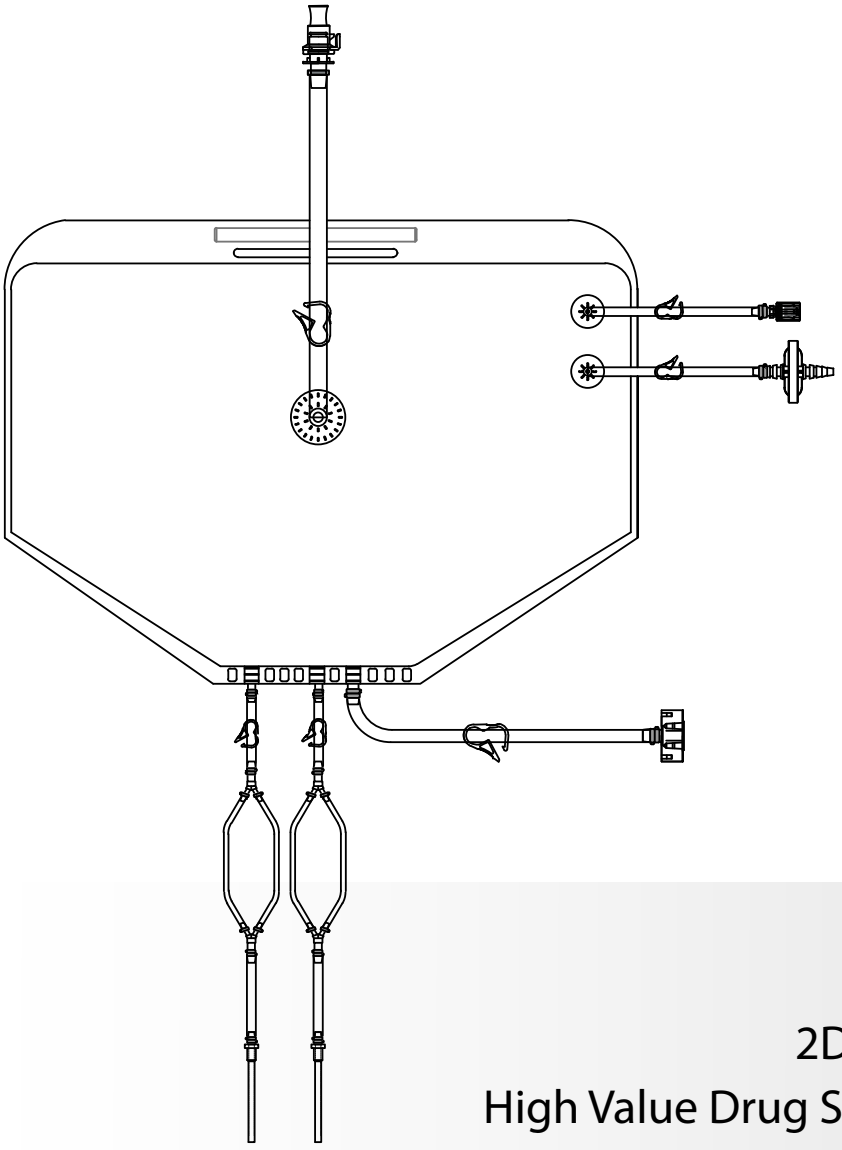
Membrane Technologies



AseptiBag™ HV

2D Single Use Tapered Bags for High Value Drug Substance and Drug Products

Biopharmaceutical drug substances and drug products are high value fluids and process owners are looking to minimize losses during transfer and filling processes.

mdi *AseptiBag™ HV* are specially designed for minimizing losses of high value drug substances and drug products in transfer and filling applications due to negligible hold up volumes.

A comparative against standard flat bottom bags used in disposable filling lines shows a significant advantage in terms of reducing product losses.

Bag Type	Hold up Volumes
Standard Flat Bottom Bags	32 mL
AseptiBag HV Tapered Bags	1 mL

AseptiFlex-D

Multilayered Film

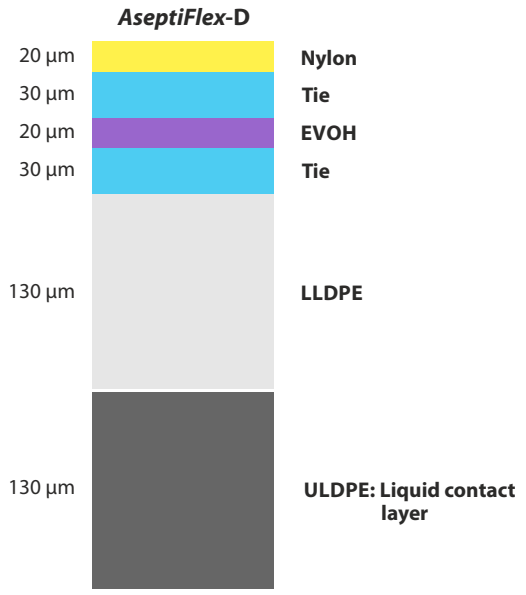
Datasheet

The MDI ***AseptiFlex*-D** Film type FBG-1 is a highly inert, multilayered polyethylene film specially designed for bioprocess applications.

The film is physically tough and inert to chemicals and solvents used in the biopharmaceutical industry and the various layers of the film provide an excellent barrier to Oxygen, CO_2 and moisture.

The contact layer is 130 µm ultra low density Polyethylene layer without any additives.

The *AseptiFlex*-D film is produced in classified areas through validated processes to ensure consistently high quality meeting various regulatory as well as functional requirements.



Deeply characterized and validated

AseptiFlex-D has been extensively characterized after gamma irradiation at 50 kGy to deliver high performance:

High strength and flexibility: for safety and integrity during handling, storage and transport

Test		Reference Standard	Average Values
Tear strength	TD	ASTM D1938	25.556 N
	MD		17.873 N
Puncture Resistance		EN14477	10.9578 N
Tensile Strength (MD)		ASTM D-882	27.0298 N/mm^2
Flex Durability Test (Gelbo)		ASTM F-392	Passes

Protection of stored liquids from oxidation, change in pH and change in concentration of critical components: with high barrier properties for Oxygen (O_2), Carbon dioxide (CO_2) and water vapour (WV)

Test	Reference Standard	Average Values
O_2 Transmission Rate	ASTM D3985-05	0.168 $cc/m^2/day$
CO_2 Transmission Rate	ASTM F 2476	<1.0 $cc/m^2/day$
WV Transmission Rate	ASTM F1249-13	0.879 $g/m^2/day$

Biocompatibility for media storage and cell growth: *AseptiFlex* film is made of plastics of Non Animal Origin and is validated for Biological Reactivity tests as per USP

Test	Reference Standard	Result
Intracutaneous Toxicity	Biological Reactivity Tests, *In Vivo*, as per USP <88>	Passes
Acute Systemic Toxicity		Passes
Muscle Implantation		Passes
Cytoxicity	Biological Reactivity Tests, *In Vitro*, USP <87>	Passes

No impact on purity of process fluids: Very low extractable profile

Test	Reference Standard	Result
Non Volatile Residue	as per USP <661>	Passes
Heavy Metals	as per USP <661>	Passes
Buffering Capacity	as per USP <661>	Passes
Effect on WFI	as per USP <1231>	Passes

AseptiBag™ HV

Quality Assurance

Datasheet

mdi quality management system emphasizes on quality by design rather than by end product testing only. Robust processes are developed for product manufacturing and are continuously monitored to ensure that the products meet their predetermined specifications and lot to lot reproducibility is ensured.

mdi *AseptiBag*™ HV single use bags are produced by trained personnel in validated ISO class 7 facilities under ISO 9001 quality management systems using validated production processes.

Each lot has well compiled batch manufacturing records that ensure complete traceability of raw materials, machines, in process controls, personnel and quality control test data.

These are tested and validated as per international standards and guidelines such as CFR, ASTM, ISO and USP and supported by well designed, state of art physical, chemical and microbiology laboratories.

100% Integrity Tested

Each *AseptiBag*™ HV is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Pressure, Temperature Endurance

AseptiBag™ *HV* systems are validated to endure operating pressure and wide temperature conditions which may be encountered during use.

These bags are also validated for burst pressure with liquid to ensure user as well as product safety in case of inadvertent pressure build-up.

Bioburden Testing

Device bioburden is tested as per ISO 117 37-1 and assured to be <1000 cfu/bag.

Biosafety

Passes Biological Reactivity test, In-Vivo, as per USP <88> for Class VI plastics

Passes the Biological Reactivity Tests, In Vitro for Cytotoxicity as described in USP <87>

Endotoxin Testing

Aqueous extracts exhibit <0.125 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Extractables

Extractables/leachables from sterile containers, used at various stages of a biopharmaceutical manufacturing process, will add on and may impact the impurity profile of the desired product.

The Extractable study was performed as per **Biophorum Best Practices Guide for Extractable Testing of Polymeric Single-Use Components used in Biopharmaceutical Manufacturing.**

AseptiBag™ *HV* systems are validated to exhibit very low extractables under harsh extraction conditions.

Identification and Traceability

The Part Number for these bags incorporates the drawing number in which this bag shall be used.

For example:

B2BA **A9893** EXR

A9893 represents the drawing number.

AseptiBag™ HV

Datasheet

Specifications

Materials of Construction

Bag Film

AseptiFlex™ D film

Storage Temperature

-20°C to 45°C

Sterilization

Gamma Sterilizable upto 50 kGy

Sterility

The gamma sterilization process has been validated as per ISO 11137 to ensure a sterility assurance level (SAL) of 10^{-6}

Bacterial Endotoxin

Aqueous extracts exhibit < 0.125 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Biosafety

Passes the Biological Reactivity Tests, *In Vivo* for Class VI plastics as described in USP <88>.

Passes the Biological Reactivity Tests, *In Vitro* for Cytotoxicity as described in USP <87>.

Fiber Release

Passes microscopic test for fibers

Particle Release

Complies with USP <788> test for particulate matter in injections

Effect on WFI

Does not affect the quality of Water for Injection (passes tests as per USP <661>)

Extractable Studies

The Extractable study was performed as per **Biophorum Best Practices Guide for Extractable Testing of Polymeric Single-Use Components used in Biopharmaceutical Manufacturing.**

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