Membrane Technologies

PATENT APPLIED

AseptiBag™ ULO^{+}

2D Single Use Systems for Storage and Transfer of Light Sensitive Fluids

Many biopharmaceutical drug substance/products, process intermediates and also chemically defined media (for mammalian cell culture) are light sensitive.

Exposure of light sensitive drugs to UV or visible light, may result in degradation of drug molecules that may impact patient safety. In case of light sensitive media, degradation of vital ingredients such as vitamins can reduce process efficiencies in mammalian cell expression systems.*

mdi ***AseptiBag***™ ULO^{+} systems are specially designed to provide validated and reliable storage and transfer solutions for light sensitive media as well as drugs for biopharmaceutical processes.

*Media photo-degradation in pharmaceutical biotechnology – impact of ambient light on media quality, cell physiology, and IgG production in CHO cultures

AseptiFlex™-T$^+$

Datasheet

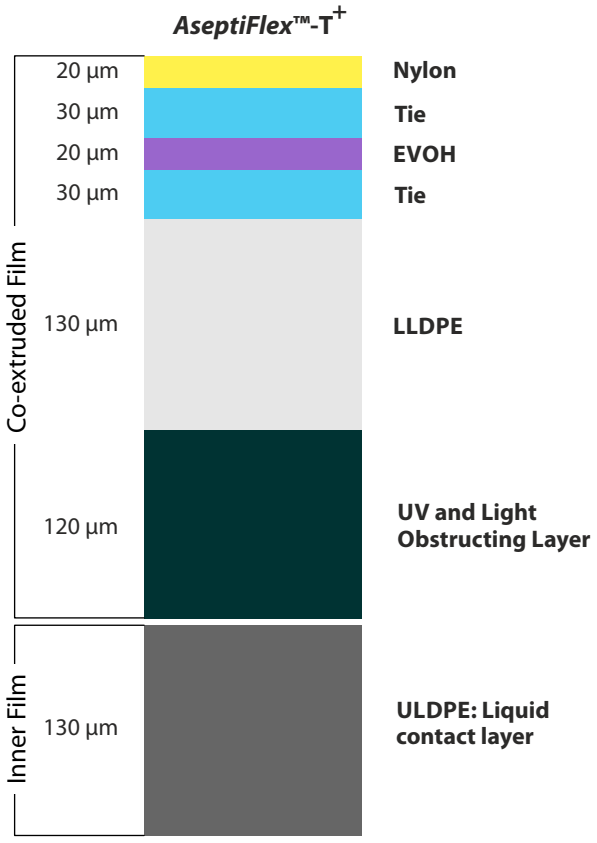
The MDI ***AseptiFlex*™-T$^+$** Film is a highly inert film specially designed for bioprocess applications involving light sensitive drugs and chemically defined proprietary media.

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 UV and light obstructing layer, co-extruded with the outer barrier layer minimizes transmission of light within the wavelength range of 200 nm to 780 nm.

The contact layer is 130 µm ultra low density Polyethylene (ULDPE) layer without any additives and ensures very low extractables.

The *AseptiFlex*™T$^+$ 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-T$^+$ 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 N
	MD		18 N
Puncture Resistance		EN14477	42 N
Tensile Strength (MD)		ASTM D-882	27 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 storage of media, drug substances and drug products: *AseptiFlex*™ T+ 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

Unique Feature

AseptiBag™ *ULO*+ are designed to protect light sensitive fluids with a unique layer for minimizing UV and light transmission. These bags have been tested for transmittance of UV (200nm - 400 nm) as well as visible light (400nm-780nm) using a spectrophotometer with a wavelength accuracy of ±0.1nm.

The following table show the comparison between transmittance of UV and visible light with standard *AseptiBag*™ and *AseptiBag*™ *ULO*+.

Bag Type		*AseptiBag*™	*AseptiBag*™ *ULO*+
		Transmittance (%)	
UV Light	<250nm	> 4 %	< 0.08 %
	250 nm - 400 nm	> 46 %	
Visible Light	(400 nm - 780 nm)	> 70 %	< 0.008%

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™ ULO+

Datasheet

Specifications

Materials of Construction

Bag Film	*AseptiFlex*™ T+ film
Connection ports	Polycarbonate
Clamps	Polyester
Tubing	Platinum cured silicone

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**

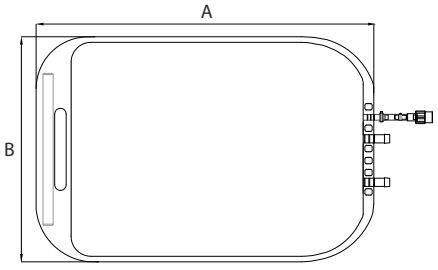
Available Sizes
3 mL, 10 mL, 50 mL, 100 mL, 250 mL, 500 mL, 1 L, 2 L, 3L, 5 L, 10 L, 20 L and 50 L

Fill Volume*
mdi *AseptiBag*™ ULO+ are designed for an overfill volume of ≥ 10% over the specified bag size (volumes).

*Overfilling may result in leakages under freezing conditions.

Dimensions

Bag Size	A	B
3 mL	75 mm	55 mm
10 mL	90 mm	60 mm
50 mL	157 mm	87 mm
100 mL	179 mm	92 mm
250 mL	189 mm	134 mm
500 mL	226 mm	155 mm
1 Litre	275 mm	200 mm
2 Litre	350 mm	200 mm
3 Litre	378 mm	247 mm
5 Litre	410 mm	319 mm
10 Litre	620 mm	322 mm
20 Litre	520 mm	580 mm
50 Litre	860 mm	582 mm



End Connections

Size	3 mL	10 mL to 250 mL	500 mL to 50 L
Inlet	Female Luer Lock	Female Luer Lock	Male Quick Connector
Outlet	-	Male Luer Lock	Male Quick Connector

Sampling Port
Needleless

Tube Length

Tube	Length		
	3 mL	**10 mL to 250 mL**	**500 mL to 50 L**
Inlet	2 Inch	4 Inch	6 Inch
Outlet	-	4 Inch	6 Inch
Sampling	-	-	6 Inch

Customization

The 500 mL to 50 litre storage bags can be customized to suit user requirements. Female quick connector can be provided for inlet port/outlet port and rubber septum for sampling port.

Larger sizes in 2D *AseptiBag*™ ULO+ are available as per user requirements.

AseptiBag™ ULO+

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*™ ULO+ single use storage and transfer systems 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*™ ULO+ is tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Pressure, Temperature Endurance

AseptiBag™ ULO+ 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

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™ ULO+ systems are validated to exhibit very low extractables under harsh extraction conditions.

Package Integrity

AseptiBag™ ULO+ systems are double packed in polybags to ensure package integrity during transit as well as to prevent contamination while transferring to clean room assembly or process areas.

Certificate of Quality

Each lot is accompanied with a Certificate of Quality and the lot number is mentioned on the packaging of each *AseptiBag*™ ULO+ storage and transfer system to ensure traceability at the user's end.

AseptiBag™ ULO+

Datasheet

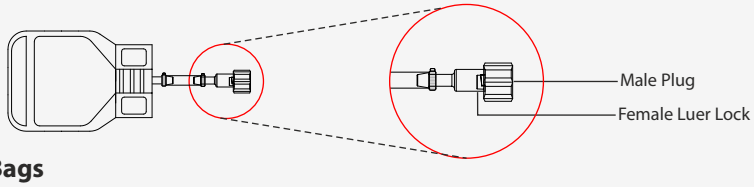
Ordering Information

For 3 mL Bags

Type		Bag Size		Inlet Port		X	XXX	Tube		X	Sterility		Pack Size	
	Code		Code		Code				Code			Code		Code
AseptiBag™ ULO+	ABUP	3 ml	U	Female Luer Lock	M			Platinum Cured Silicone	X		Gamma Sterile	3	10	02

Example

ABUP	U	M	X	XXX	X	X	3	02

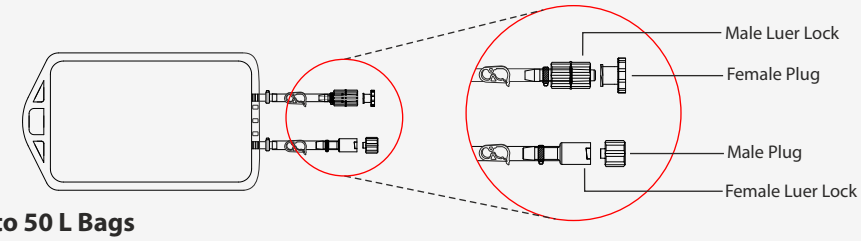


For 10 mL to 250 mL Bags

Type		Bag Size		Inlet Port		Outlet Port		XXX	Tube		X	Sterility		Pack Size	
	Code		Code		Code		Code			Code			Code		Code
AseptiBag™ ULO+	ABUP	10 ml	T	Female Luer Lock	M	Male Luer Lock	L		Platinum Cured Silicone	X		Gamma Sterile	3	10	02
		50 ml	S												
		100 ml	A												
		250 ml	B												

Example

ABUP	B	M	L	XXX	X	X	3	02



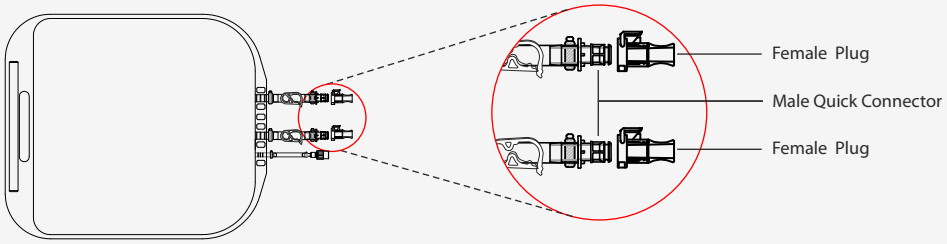
For 500 mL to 50 L Bags

Type		Bag Size		Inlet Port		Outlet Port		Sampling Port		XX	Tube		X	Sterility		Pack Size	
	Code		Code		Code		Code		Code			Code			Code		Code
AseptiBag™ ULO+	ABUP	500 mL	V	Male Quick Connector	J	Male Quick Connector	J	Needleless	N		Platinum Cured Silicone	X		Gamma Sterile	3	10	02
		1 L	C	Female Luer Lock*	M	Male Luer Lock*	L										
		2 L	D														
		3 L	W														
		5 L	E														
		10 L	F														
		20 L	G														
		50 L	H														

*Female Luer Lock and Male Luer Lock is available only for 500mL, 1L and 2L bag sizes

Example

ABUP	C	J	J	N	XX	X	X	3	02



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