AseptiBag™ LT

Storage & Transfer Bags for Low Temperatures

DATASHEET

Product Description

mdi *AseptiBag*™ LT single use storage and transfer systems are designed for cold chain applications in biopharmaceuticals. These systems are designed for low temperature storage of up to - 80 °C, as well as multiple freeze thaw applications involving high value drug substances and process intermediates.

mdi *AseptiBag*™ LT systems are made from low extractable ULDPE film, and provide robustness to ensures integrity at sub zero temperatures during freezing, storage, transportation, and thawing.

AseptiBag™ LT offers multiple advantages such as:

- Compatible with long term storage at low temperatures of up to -80 °C
- Ability to withstands multiple freeze thaw cycles
- Very low extractable profile
- High strength and flexibility
- High transparency

Applications

mdi *AseptiBag*™ LT systems are used for long term low temperature storage of:

- Process intermediates
- Drug substances
- Vaccine active raw materials (arm)
- Monoclonal Antibodies (mAbs)
- Recombinant proteins

DST ABLTXXX2505B

AseptiBag™ LT

Low Temperatures Bags

DATASHEET

DST ABLTXXX2505B

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*™ LT 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*™ LT systems are tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Pressure Endurance

AseptiBag™ LT systems are validated to endure operating pressure and burst pressure with liquid to ensure user as well as product safety in case of inadvertent pressure build-up.

Temperature Endurance

AseptiBag™ LT systems are validated to endure wide temperature conditions which may be encountered during use.

Bioburden Testing

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>.

Extractables

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

The extractable profile of mdi *AseptiBag*™ LT systems has been conducted as per BioPhorum Best Practices Guide for Extractable Testing of Polymeric Single Use Components used in Biopharmaceutical Manufacturing.

Particulate Matter

AseptiBag™ LT systems are validated for particulate matter in injections as per USP <788> and visible particulates in injections as per USP <790>.

AseptiBag™ LT

Low Temperatures Bags

DATASHEET

DST ABLTXXX2505B

Sterility Assurance

mdi *AseptiBag*™ LT systems are sterilized by gamma irradiation to provide a sterility assurance level of 10^{-6}. The sterilization process has been validated as per ISO 11137-2 which includes dose verification, dose mapping and quarterly dose audits.

The sterilization dose of 25 kGy has been substantiated through careful definition of the test samples, bio-burden testing of multiple lots of the selected test samples, calculation of verification dose and sterility testing.

Bacterial Endotoxin

Aqueous extracts exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) Test as per USP <85>

Materials of Construction

Film: Ultra-Low Density Polyethylene (ULDPE)

Operating Temperature

-80°C to 45°C

Storage temperature

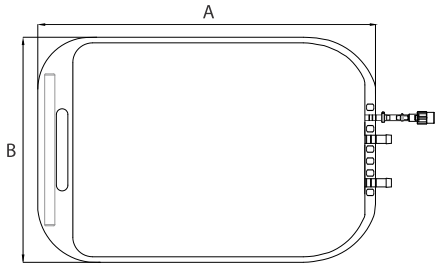
up to -80°C

Sterilization

Gamma Sterilizable upto 50 kGy

Available Sizes and Dimensions

Bag Size	A	B
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



AseptiBag™ LT

Low Temperatures Bags

DATASHEET

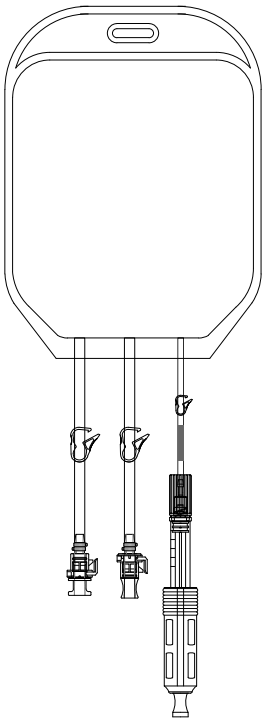
DST ABLTXXX2505B

Product Availability

mdi *AseptiBag*™ LT low temperature bags are only available as part of **mdi** single use systems.

Customization

mdi *AseptiBag*™ LT systems can be customized to suit user requirements in terms of tubing, fittings, end connections and connectors.



Product Realization Flow Chart

User Specified *AseptiBag*™ *LT* Design Specifications
User process flow requirements such as working environment, temperature conditions, tubing, fittings, end connections and connectors are established

↓

Technical Feasibility
Based on the above information and available components a technical feasibility of the Bag Assemblies are done and an initial drawing of same is submitted for user approval

↓

Design approval
- User approval of bag assemblies drawing
- Changes to finalize drawing, if required

↓

Finalized *AseptiBag*™ *LT* Bag Assemblies

CORPORATE OFFICE
Advanced Microdevices
20-21, Industrial Area, Ambala Cantt
133 006, India
E-mail: info@mdimembrane.com
Website: www.mdimembrane.com

US OFFICE
MDI Membrane Technologies INC
75 Utley Drive STE 103
Camp Hill, Pennsylvania 17011
United States of America
Website: www.mdimembranetech.com