AseptiBag™ HT

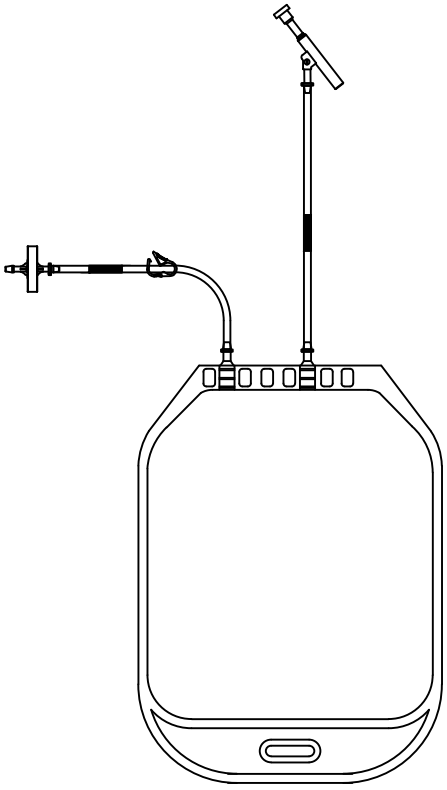
Autoclavable Sampling Bags

DATASHEET

Aseptic sampling from lab scale table top reusable bioreactors is a challenge. Reusable sampling containers connected to the bioreactor are prone to damage during autoclaving, resulting in leakages and expensive downtime.

mdi ASESS sampling systems with autoclavable AseptiBag™ HT bags are designed to withstand autoclaving temperatures (121°C-123°C) and offer a reliable solution for such applications.

mdi AseptiBag™ HT are well characterized and validated for integrity and strength, sterility, microbial ingress, endotoxins, biosafety, extractables, particulate matter that may impact the identity, strength, quality and purity of the samples.



Applications

mdi *AseptiBag*™ HT sampling bags are used for sampling from reusable bioreactors in clone selection and media optimization labs

DST ABHTXXX2505H

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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*™ HT sampling 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*™ HT sampling bags are tested for integrity to comply with validated Acceptable Integrity Test Specifications.

Pressure Endurance

AseptiBag™ HT sampling bags 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™ HT sampling bags are validated to withstand autoclaving temperatures up to 121°C.

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*™ HT sampling bags has been conducted as per BioPhorum Best Practices Guide for Extractable Testing of Polymeric Single Use Components used in Biopharmaceutical Manufacturing.

Particulate Matter

AseptiBag™ HT sampling bags are validated for particulate matter in injections as per USP <788>.

These are also validated for visible particulates in injections as per USP <790>.

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Sterility Assurance

mdi *AseptiBag*™ HT sampling bags 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: High Density Polyethylene (HDPE)

Sterilization

By Gamma Irradiation: Gamma Sterilizable upto 50 kGy

By Autoclaving: Autoclavable at 121°C for 30 minutes

Tensile Strength

19265.3 N/sq. inch

Tear Strength

Transverse Direction (TD): 19.38 N/inch

Machine Direction (MD): 22.8 N/inch

Puncture Resistance

5.50 N/sq. inch

Seal Strength

3197.5 N/sq. inch

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Product Realization Flow Chart

User Specified *AseptiBag™ HT* Design Specifications
User process requirements such as working environment, autoclaving temperature, sampling port, sampling bag size, tube lengths, vent filters etc. are established

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

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

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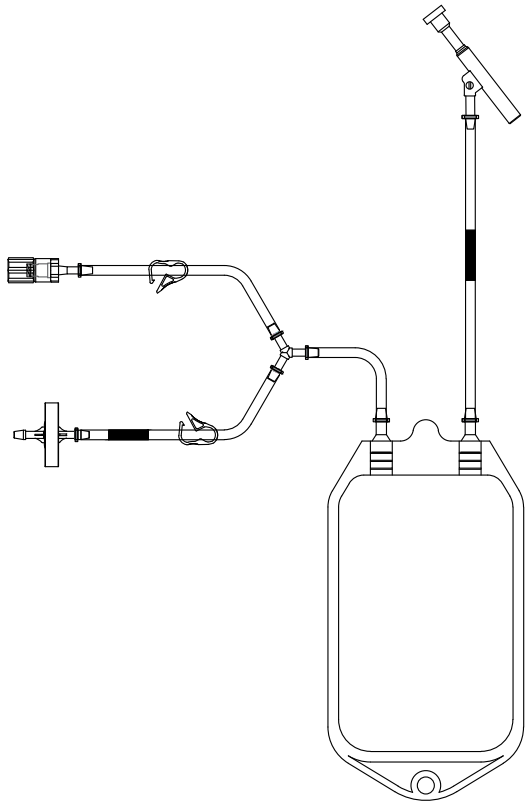
Finalized *AseptiBag™ HT* Sampling Bags

Customization

mdi *AseptiBag*™ HT sampling bags can be customized to suit user requirements in terms of bag size and tube length.



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