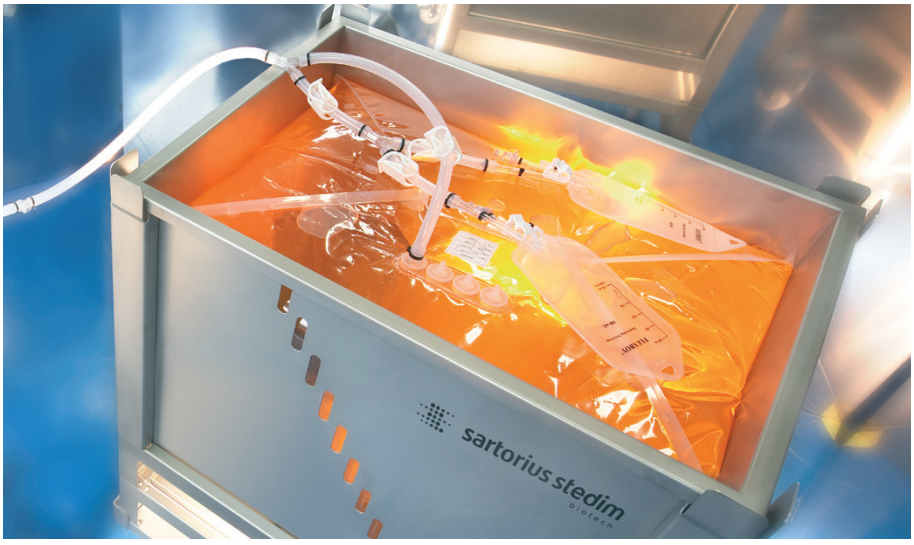
Fluid Management Systems

Integrity Testing of Flexel® 3D

Bioprocessing Bags for Drum and for Palletank



Description

Flexel® 3D Bioprocessing Bags are designed for processing, storage and transport of large volume biopharmaceutical solutions in drum and Palletank. They provide a single-use alternative to traditional stainless steel vessels in a large variety of applications. Normal process validation and in process control of the manufacturing provides a high degree of reliability of Flexel® 3D Bioprocessing Bags.

For critical storage and processing applications that require a higher degree of assurance, the integrity of each Flexel® 3D Bioprocessing Bag can be controlled with an optional test performed at Sartorius Stedim Biotech manufacturing plant.

Integrity testing

Large volume, single-use Flexel® 3D Bags are increasingly used for the handling, storage and transport of high value products, such as bulk drug substances and vaccines. For these applications, an in-process bag chamber integrity test can be performed during manufacturing at Sartorius Stedim Biotech. This in-process physical control, in combination with the microbial challenge validation study is essential to provide the highest assurance level of the bag integrity. This optional test is performed on customer request for customized bag configurations.

The integrity test method is derived from ASTM F2095: "Standard Leak Test for Nonporous Flexible Packages with Restraining Plates". A pressure decay leak test is used to detect small channel defects in the seals or pinholes in the walls of the flexible bag.

The test method is non destructive and compatible with a 100% on-line implementation in Sartorius Stedim Biotech grade C clean rooms. The in-process test is performed on sealed bag chambers after the welding of the bag port and before assembly with the fill and drain lines.

Features & Benefits

Applicable to Flexel® 3D Bags for Drum and Palletank (50 L – 200 L)	Covers most common volume bags for critical applications.
Non destructive testing	Safe and robust 100% testing is performed
High resolution, reproducibility, repeatability	High assurance level of the bag chamber integrity
Rapid, online testing	100% testing
Validated	High assurance level of bag integrity
Traceable	Documented batch record and certificate of release

Specifications

Integrity tested Flexel® 3D Bags for Drum

Bag Chamber	S40 multiple layer film construction, including EVOH gas barrier layer, and a PE contact layer
Volumes	50 L, 100 L & 200 L
Port tubing	Top port: 4 × port tubing with a ½" hose barb in position 1 Bottom port: No port
Tubing	Silicone, TPE

Integrity tested Flexel® 3D Bags for Palletank

Bag Chamber	S40 multiple layer film construction, including EVOH gas barrier layer, and a PE contact layer
Volumes	100 L & 200 L
Port tubing	Top port: 4 × port tubing with a ½" hose barb in position 1 Bottom port: 1 port tubing
Tubing	Silicone, TPE

Applications
Flexel® 3D Bioprocessing Bags are constructed from S40, a multi-layer film that provides a strong structure with low gas permeability and high chemical resistance for the safe processing of a wide range of biopharmaceutical fluids in a variety of applications. Typical applications requiring a 100% in-process integrity testing include:

- Bulk intermediate filtration & hold
- Bulk drug substance storage and transport
- Final fill and finish operations

The integrity of large volume sterile single-use bags is of paramount importance for the handling and storage of biopharmaceutical products. The single use container must act as an effective barrier to microorganism to insure the sterility of the stored solutions. The integrity testing performed during the manufacturing of Flexel® 3D Bioprocessing Bags considerably increases the security and safety of single use biopharmaceutical processes.

Security of Supply
Sartorius Stedim Biotech has established multiple manufacturing sites with consistent industrial processes. The expertise of designing Single Use solutions combined with collaborative supplier management and customer demand planning assures a state of the art product supported by a robust supply chain that can cope with strong market growth.

Validation
Flexel® 3D Bags have been qualified applying the most comprehensive and innovative test regimes. Biological, chemical and physical tests combined with extensive extractable testing provide users of Flexel® 3D Bags with data representing a wide range of process fluids in a variety of processing conditions.

Full compliance with ISO11137 allows for a validated claim of sterility on all Sartorius Stedim Biotech single-use products with a sterility assurance level of 10^{-6} over the shelf life.

The objective of the air leak test is to check the integrity of the bag seals and port welds and identify possible damages of the film. This in-process test is performed during manufacturing on a 100% basis for each type of bag, using 0.2 µm filtered clean air. The pressure decay during the test is measured and compared to an acceptance criteria determined during the qualification of the method.

The test can securely distinguish between integral and non-integral bags. In order to define the acceptance criteria, measurements were evaluated with a large range of calibrated defects. Pinholes are associated with slight pressure decay during the test period. Large pressure decays are generated by large sealing defects.

Quality Assurance
Sartorius Stedim Biotech Quality Systems for Single-use products follow applicable ISO and FDA regulations. Design, Manufacture and Sterilization processes are conducted under conditions that mirror biopharmaceutical operations and meet cGMP requirements. Flexel® 3D Bags for Palletank and for Drum are tested for compliance to:

- USP <87>: Biological reactivity tests, in Vitro
- USP <88>: Biological reactivity tests, in Vivo
- USP <661>: Tests for plastic
- USP <788> and E.P. 2.9.19: Particulate matters in injections
- USP<85> and E.P.2.6.14: Bacterial endotoxins
- ISO 11737: Bioburden
- ISO 11137: Sterilization of Medical Devices

Implementation
Integrity testing is implemented for customized Flexel® 3D Bags upon customer request.

The integrity test can be applied to new or existing Flexel® 3D Bag configurations. For an existing configuration, implementation of the integrity test in production is initiated with a "Product Modification Request (PMR)". For a new bag configuration, the demand for the integrity test is reported in the user requirements of the new product.

Ordering information
Contact your local Sartorius Stedim Biotech sales representative for ordering information.

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