

Point-of-Use Leak Test Flexsafe® 3D Storage and Shipping Bags



Product Information

The Point-of-Use Leak Test (PoU-LT) improves the assurance of integrity of bags used in critical drug substance and drug product process steps of cGMP commercial production.

Thanks to an accurate pressure decay measurement equipment and a unique, patented technology to avoid masking effect and reduce the heat transfer, the PoU-LT ensures a fast, easy-to-use and highly reliable leak test just before use.

Safe

Bags breakage during shipping and handling and the loss of production material have been detected as the main concerns by several end-users surveys on single-use. The PoU-LT performed with the Sartocheck® 4 plus Bag tester provides a non-destructive and safe leak test of Flexsafe® 3D Storage and Shipping Bags already installed for use in the Palletank for storage, in-process or shipping.

Fast & Easy to Use

The well-known ASTM F2095 standard pressure decay leak test at point of use and the well-established Sartocheck® 4 plus Bag tester technology make the PoU-LT easy to implement.

In addition, the Sartocheck® Fast Filling Kit allows to save up to 15 minutes of total test time with limited extra manipulation.

Reliable

The unique patented porous spacers that perfectly fit the Palletank for Storage and Shipping shape avoid masking effect due to direct contact between the bag and the container improving the reliability.

A robust parameters validation is proposed for the standard Flexsafe® 3D Storage and Shipping Bags up-to 500 L. The test parameters have been optimized and validated with a 6-sigma confidence level in order to reliably detect defect down-to 100 µm, tested twice (with non-defective and defective samples).

Test Description

Sartorius PoU-LT test is based on the well-established pressure decay measurement derived from the ASTM F2095 test method using the Sartocheck® 4 plus Bag tester technology.

Flexsafe® 3D Storage and Shipping Bags are completely filled with air at low pressurization. Once the pressure stabilized in the bag, the valves are closed. A Passed | Failed message appears at the end of the test to indicate a defect presence within the full system. The pressure drop limit is determined by a robust validation plan that could detect down to 100 µm defect sizes. Furthermore a PoU-LT line is pre-assembled to the Flexsafe® 3D Storage and Shipping Bags for easy and safe connection to the Sartocheck® 4 plus Bag tester. Once the leak test finished, the air easily escape through the vent filter to keep the bag sterility during liquid filling.

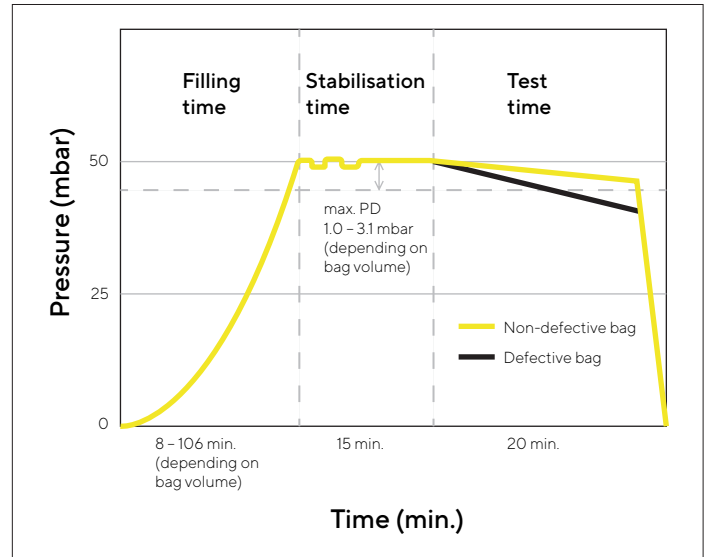


Figure 1: Pressure decay test cycle

Technical Specifications

PoU-LT Parameters

Volume		100 L	200 L	500 L
Sensitivity		100 µm	200 µm	200 µm
Test pressure			50 mbar	
Filling time	With Sartocheck® 4 Plus Bag Tester	10 min	20 min	50 min
	With Sartocheck® Fast Filling Kit	8 min	15 min	35 min
Stabilization time			10 min	
Test time		25 min	13 min	35 min
Max. pressure drop*		2.5 mbar	3.0 mbar	3.0 mbar

* Rounded up-to 1 digit

Flexsafe® 3D Storage and Shipping Bag

Flexsafe® 3D Storage and Shipping Bags intended to be leak tested need a Sartopore® Air sterilizing grade vent filter line pre-assembled to perform the test without breaking the sterility of the system. TPE tubing is used to disconnect the filter line after testing, using a BioSealer®.

PoU-LT is applicable to Flexsafe® Storage and Shipping Bags from 50 L up-to 500 L volumes



Figure 2: Example of a Flexsafe® 3D Bag fitted with the PoU-LT line

Sartocheck® 4 plus Bag tester

The Sartocheck® 4 plus Bag tester is specially designed for bags testing based on the well-established ASTM F2095-07 Pressure Decay Test. It allows leak testing of bags connected through a sterilizing-grade filter: Sartopore® Air.

Measuring Ranges

Test pressure	10 – 300 mbar 0.145 – 4.350 psi
Pressure drop	0.1 – 300 mbar 0.0014 – 4.350 psi

Measuring Accuracy

Pressure drop	±0.3%
Operating Conditions	Ambient temperature ±15°C to +35°C Rel. humidity 10 – 80

Sartocheck® Bag tester fleeces

Sartocheck® Bag tester fleeces are single-use porous spacers avoiding any contact of the bag film with the stainless steel Palletank during the test. As such, any potential masking effect is eliminated. The masking effect can occur when a leak in the plastic film is pressed against a surface and therefore is blocked.



Set of Sartocheck® Bag tester fleeces

Packaging	Individual PE-bag
Material	Polypropylene
Content	4 Fleeces with clamp

Testing tube for 3D bags

The testing tube for 3D bags allows the connection to the Sartocheck® 4 plus Bag tester and air filling of the Flexsafe® 3D Storage and Shipping Bags via the Sartopore® Air sterilizing grade filter.



Ordering Information

Flexsafe® 3D Storage and Shipping Bags

Palletank® for Storage and Filter Holder

- Palletank for Storage, Order No. refer to Brochure "Flexsafe® 3D storage Pre-designed Solutions"
- Filter holder for Palletank, Order No.: FXC301477

Sartocheck® 4 plus Bag tester

Sartocheck® 4 plus Bag tester	26288---BT
Sartocheck® 4 plus Bag tester MultiUnit	26288---BM
Testing tube for 3D bags	26288---BT3D
Sartocheck® Fast Filling Kit	DZ--MXFFK

Sartocheck® Bag tester fleeces

Test equipment	Order No.
Porous spacer for Flexsafe® 3D	
▪ 100 L & 200 L	DZ200L-PTSIT
▪ 500 L bag	DZ500L-PTSIT

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