

Point-of-Use Leak Test Flexsafe® Mixing 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 safe, easy-to-use and highly reliable leak test just before use.

Safe

Flexsafe® mixing 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 Sartochek® 4 plus Bag Tester provides a non-destructive and safe leak test of Flexsafe® mixing bags already installed for use in the Palletank® for Mixing.

Fast & Easy to Use

The well-known ASTM F2095 standard pressure decay leak test at point of use and the well-established Sartochek® 4 plus Bag Tester technology make the PoU-LT easy to implement. The Sartochek® fast filling kit pre fills the Flexsafe® mixing bags with air shortening the test time.



Reliable

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

A robust parameter validation is proposed for the standard Flexsafe® mixing bags up-to 1,000 L. The test parameters have been optimized and validated with a 6-sigma confidence level in order to reliably detect defects down-to 50 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® mixing 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 50 µm defect sizes. Furthermore a PoU-LT line is pre-assembled to the Flexsafe® mixing bags for easy and safe connection to the Sartocheck® 4 plus Bag Tester. Once the leak test finished, the air easily escapes through the vent filter to keep the bag sterility during liquid filling. The Sartocheck® fast filling kit has been developed to pre fill Flexsafe® mixing bags with air shortening the test time.

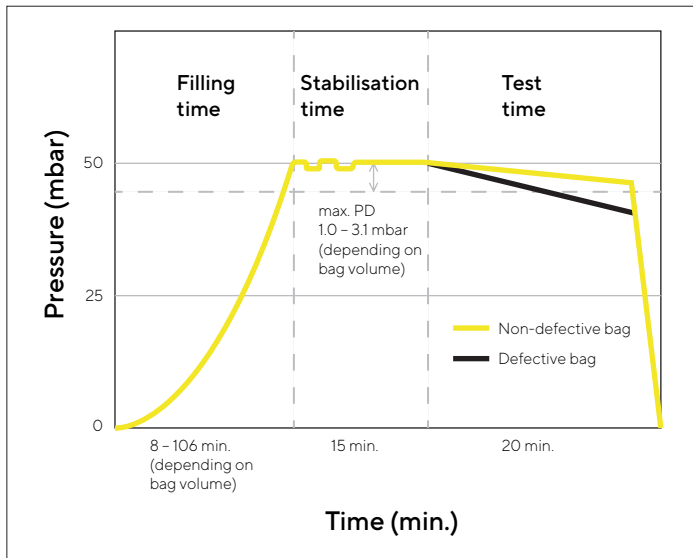


Figure 1: Pressure decay test cycle

Technical Specifications

PoU-LT Parameters

Volume [L]	50	100	200	400	650	1000
Sensitivity [µm]	50	100	100	200	400	400
Test pressure [mbar]	50	50	50	50	50	50
Max. filling time [min] w/ Sartocheck®	8	13	24	44	73	106
Stabilization time [min]	15	15	15	15	15	15
Test time [min]	20	20	20	20	20	20
Total time [min]	43	48	59	79	108	141
Total time w/ Fast filling [min]	40	44	53	66	82	95
Max. pressure drop* [mbar]	1.0	2.5	1.6	1.8	3.1	2.9

* Rounded up-to 1 digit

Flexsafe® Mixing Bag

Flexsafe® mixing 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. C-Flex® TPE tubing is used to disconnect the filter line after testing, using a Biosealer®.

PoU-LT is compatible with Flexsafe® mixing bags equipped with Flexsafe® Pro Mixer, LevMixer® and magnetic technologies.

PoU-LT is applicable to Flexsafe® mixing bags from 50 L up-to 1,000 L volumes

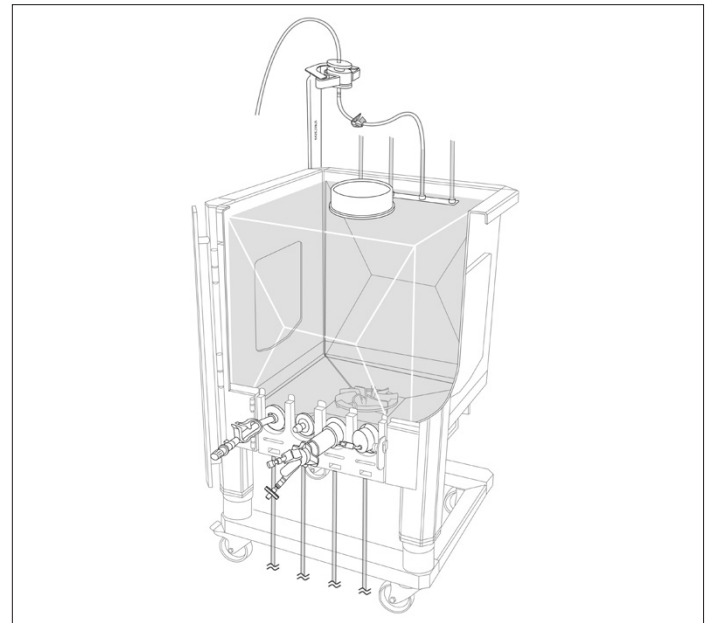


Figure 2: Example of a Flexsafe® Pro Mixer bag fitted with the PoU-LT line

Sartocheck® 4 plus Bag Tester

The Sartocheck® 4 plus Bag Tester is specially designed for bags testing based on the well-established ASTM F2095 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	1× Fleece front 3× Fleece side (left back right) 1× Fleece bottom 1× Fleece disc (only required when using a LevMixer® or a Magnetic Mixer Bags)

Sartocheck® Bag Tester clamp

Clamps aim at maintaining the Sartocheck® Bag Tester fleeces in proper position.



Set of clamps for Palletank® for Mixing single-walled



Set of clamps for Palletank® for Mixing jacketed

Set of Sartocheck® Bag Tester clamp

Packaging	Individual PE-bag
Material	Stainless steel
Content	For Palletank® for Mixing single-walled: 2× clamps, size 22 - 33 8× clamps, size 40 - 55 For Palletank® for Mixing jacketed: 8× clamps, size 75

Testing Tube for 3D Bags

The testing tube for 3D bags allows the connection to the Sartochek® 4 plus Bag Tester and air filling of the Flexsafe® mixing bags via the Sartopore® Air sterilizing-grade filter. The testing tube for 3D bags is also used with the Sartochek® fast filling kit.



Sartochek® Fast Filling Kit

The Sartochek® fast filling kit prefills Flexsafe® mixing bags with air shortening the test time.



Sartochek® Fast Filling Kit

Minimum inlet pressure	4,5 bar
Maximum inlet pressure	35 bar
Bag filling pressure	45 mbar

Ordering Information

Flexsafe® Mixing Bags

Flexsafe® mixing bags equipped with a PoU-LT line can be configured using Sartorius configurator.

Palletank® for Mixing and Filter Holder

- Palletank® for Mixing, Order No. refer to brochure "Flexsafe® Pro Mixer Pre-designed Solutions"
- Filter holder for Palletank®, Order No.: FXC301585

Sartochek® 4 plus Bag Tester

Sartochek® 4 plus Bag Tester	26288---BT
Sartochek® 4 plus Bag Tester MultiUnit	26288---BM
Testing tube for 3D bags	26288---BT3D
Sartochek® fast filling kit	DZ-----MXFFK

Sartochek® Bag Tester fleeces

Flexsafe® mixing bag volume	Quantity of fleeces set per box	Order No.
50 L	5	DZ050L-MXSIT
100 L	4	DZ100L-MXSIT
200 L	3	DZ200L-MXSIT
400 L	3	DZ400L-MXSIT
650 L	3	DZ650L-MXSIT
1,000 L	2	DZ001K-MXSIT

Sartochek® Bag Tester clamps


Palletank® for Mixing type	Quantity of clamps set per box	Order No.
Single-Walled	1	DZ-----MXCSW
Jacketed	1	DZ-----MXCDW

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